

**8.01.58 Cranial Electrotherapy Stimulation and Auricular Electrostimulation****Original Policy Date:** July 6, 2012**Effective Date:** April 1, 2024**Section:** 8.0 Therapy**Page:** Page 1 of 25**Policy Statement**

- I. Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is considered **investigational** in all situations.
- II. Electrical stimulation of auricular acupuncture points is considered **investigational** in all situations.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

**Policy Guidelines**

There are no CPT codes specific to electrical stimulation of auricular acupuncture points. The following CPT codes might be used:

- **97813:** Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
- **97814:** Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

The following codes might also be used for auricular stimulation:

- **63650:** Percutaneous implantation of neurostimulator electrode array, epidural
- **64555:** Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
- **L8680:** Implantable neurostimulator electrode, each

The following HCPCS code is specific to auricular stimulation:

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

**Effective January 1, 2024**, the following HCPCS code for cranial electrotherapy and auricular stimulation has been added:

- **E0732:** Cranial electrotherapy stimulation (CES) system, any type

**Effective January 1, 2024**, the following HCPCS code for cranial electrotherapy stimulation has been **deleted**:

- **K1002:** Cranial electrotherapy stimulation (CES) system, any type

There is a HCPCS code that may represent supplies for HCPCS code K1002:

- **A4596:** Cranial electrotherapy stimulation (CES) system supplies and accessories, per month

The following CPT code was created to report transcutaneous auricular neurostimulation (tAN) which is a new therapy to aid in the relief of opioid withdrawal symptoms.

- **0783T:** Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment

## 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.

## Related Policies

- Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy
- Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
- Transcutaneous Electrical Nerve Stimulation

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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. Devices cleared since 2000 are summarized in Table 1.

FDA product code: QJQ.

**Table 1. Cranial Electrotherapy Stimulation Devices Cleared by the U.S. 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
Elaxoma Medic™	Redplane AG	05/21/2008	K070412	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness	04/05/2007	K062284	Insomnia, depression, anxiety

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

Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing by the FDA through the 510(k) process. Devices cleared since 2000 are summarized in Table 2.

FDA product codes: BWK, PZR.

**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 VI	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 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®	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
P-Stim	Biegler GMBH	06/27/2014	K140788	Practice of acupuncture by qualified practitioners as determined by the states

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

<sup>a</sup> "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

### 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. 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. 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.

## Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## Cranial Electrotherapy Stimulation for Acute or Chronic Pain

### Clinical Context and Therapy Purpose

The purpose of cranial electrotherapy stimulation (CES) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management and other conservative therapies, in individuals with acute or chronic pain.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with acute or chronic pain.

### *Interventions*

The therapy being considered is CES.

**Comparators**

Comparators of interest include medical management and other conservative therapies. Treatments include physical exercise, stress management, and analgesic and narcotic medication therapy.

**Outcomes**

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity. While studies described below have varying lengths of follow-up, longer follow-up is necessary to fully observe outcomes.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

**Review of Evidence****Headache**

Klawansky et al (1995) published a meta-analysis of 14 RCTs comparing CES with sham for the treatment of various psychological and physiological conditions.<sup>2</sup> The literature search, conducted through 1991, identified 2 trials evaluating CES for the treatment of headache. Pooled analysis of the 2 trials (N=102 patients) favored CES over placebo (0.68; 95% confidence interval [CI], 0.09 to 1.28).

A Cochrane review by Bronfort et al (2004) assessed noninvasive treatments for headaches; reviewers conducted a literature search through November 2002.<sup>3</sup> They identified 1 poor quality, placebo-controlled, randomized trial (N=100) of CES for a migraine or a tension-type headache. Results from the trial showed greater reductions in pain intensity in the CES group than in the placebo group (effect size, 0.4; 95% CI, 0.0 to 0.8). A 2014 update to this review has been withdrawn due to the desire to replace the review with 3 separate reviews; however, these were unable to be completed.<sup>4</sup>

**Chronic Pain**

A Cochrane review by O'Connell et al (2014) evaluated noninvasive brain stimulation techniques for chronic pain and conducted a literature search through July 2013.<sup>5</sup> Reviewers identified 11 randomized trials of CES for chronic pain. A meta-analysis of 5 trials (N=270 participants) found no significant difference in pain scores between active and sham stimulation (standard mean difference [SMD], -0.24; 95% CI, -0.48 to 0.01) for the treatment of chronic pain. A 2018 update did not find additional trials for CES.<sup>6</sup>

Subsequent to the Cochrane review by O'Connell et al (2018),<sup>6</sup> Ahn et al (2020) published a double-blind, randomized, sham-controlled pilot study of the feasibility and efficacy of remotely supervised CES via secure videoconferencing in 30 older adults with chronic pain due to knee osteoarthritis.<sup>7</sup> Mean age was 59.43 years. Cranial electrotherapy stimulation was delivered via the Alpha-Stim M Stimulator, which was preset at 0.1 mA at a frequency of 0.5 Hz and applied for 1 hour daily on weekdays for 2 weeks. The sham electrodes were identical in appearance and placement, but the stimulator did not deliver electrical current. The study was conducted in a single center in Houston. All 30 participants completed the study and were included in the outcome analyses. For the primary outcome of clinical pain at 2 weeks as assessed by a Numeric Rating Scale, a significantly greater reduction occurred in the active CES group (-17.00 vs. +5.73;  $p < .01$ ). No patients reported any adverse effects. Important relevancy limitations include lack of assessment of important health outcomes or long-term efficacy. An important conduct and design limitation is that it is unclear how convincing

the sham procedure was as it did not involve any feature designed to simulate a tingling sensation and give the patient the feeling of being treated (i.e., subtherapeutic amplitude, initial current slowly turned to zero). Thus, findings may be subject to the placebo effect. This trial was also limited by the small number of participants. These limitations preclude drawing conclusions based on these findings.

### **Section Summary: Acute or Chronic Pain**

Systematic reviews of randomized trials were identified testing CES for the treatment of headache, with analyses marginally favoring CES over placebo. A meta-analysis of 5 trials comparing CES with sham for the treatment of chronic pain found no difference between the treatment and sham groups. A 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 design and conduct limitations. Additional evidence is needed to permit conclusions about whether CES improves outcomes for individuals with chronic pain.

## **Cranial Electrotherapy Stimulation for Psychiatric, Behavioral, or Neurologic Conditions**

### **Clinical Context and Therapy Purpose**

The purpose of CES is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in individuals with psychiatric, behavioral, or neurologic conditions.

The following PICO was used to select literature to inform this review.

### ***Populations***

The relevant population of interest is individuals with psychiatric, behavioral, or neurologic conditions.

### ***Interventions***

The therapy being considered is CES.

### ***Comparators***

Comparators of interest include standard therapy. Treatment includes psychiatric counseling.

### ***Outcomes***

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity. While studies described below have varying lengths of follow-up, longer follow-up is necessary to fully observe outcomes.

## **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## **Review of Evidence**

### **Anxiety and Depression**

#### **Systematic Reviews**

An older meta-analysis by Klawansky et al (1995) described in the Headache section above, analyzed 8 trials (N=228 patients) comparing CES with sham for the treatment of anxiety.<sup>2</sup> While only 2 studies independently reported CES to be more effective than sham, the pooled estimate found CES to be

significantly more effective than sham ( $-0.59$ ; 95% CI,  $-0.95$  to  $-0.23$ ). More recently, Price et al (2021) published a meta-analysis evaluating CES for the treatment of depression and/or anxiety and depression (Tables 3, 4, and 5).<sup>8</sup> Five RCTs and 12 open-label, non-randomized studies that utilized Alpha-Stim were included. When considering pooled data from RCTs, results demonstrated that the mean depression level at posttest for the CES group was  $-0.69$  standard deviations lower than the mean depression level for the sham stimulation group, which corresponds to a medium effect size. Pooled data from nonrandomized studies showed a smaller effect of  $-0.43$  standard deviations in favor of CES. A 2022 meta-analysis identified 11 RCTs evaluating CES in patients with anxiety ( $N=794$ ).<sup>9</sup> Anxiety symptoms were significantly reduced with CES versus control (Hedges'  $g$ ,  $-0.625$ ; 95% CI,  $-0.952$  to  $-0.298$ ;  $p<.001$ ;  $I^2=78.6\%$ ). Depressive symptoms were also reduced in these patients (Hedges'  $g$ ,  $-0.648$ ; 95% CI,  $-1.062$  to  $-0.234$ ;  $p=.002$ ;  $I^2=80.31\%$ ). The analysis is limited by high variability in the number of sessions (14 to 126), session duration (10 to 60 minutes), outcomes scale, and the small number of patients in each trial.

**Table 3. Comparison of Trials/Studies Included in Systematic Reviews and Meta-analyses**

Study	Price et al (2021) <sup>8</sup>	Ching et al (2022) <sup>9</sup>
Amr (2013)		



Study	Dates	Trials	Participants	N (Range)	Duration
IV TR, DSM-V, or ICD10.					

DSM: Diagnostic and Statistical Manual or Mental Disorders; DSM-TR: Diagnostic and Statistical Manual or Mental Disorders-Text Revision; ICD: International Classification of Diseases; NR: not reported; RCT: randomized controlled trial.

**Table 5. Systematic Reviews and Meta-analyses Results**

Study	Effect size using RCT data	Effect size using nonrandomized study data
<b>Price et al (2021)<sup>8</sup></b>		
Total N	242	1173
Effect	-0.69	-0.43
SE	0.14	0.03
P (p)	0 (.85)	81.66 (NR)
<b>Ching et al (2022)<sup>9</sup></b>		
<i>Anxiety</i>		
N	692	
Effect	-0.625	
95% CI	-0.952 to -0.298	
p	<.001	
<i>Depression</i>		
N	552	
Effect	-0.648	
95% CI	-1.062 to -0.234	
p	.002	

CI: confidence interval; NR: not reported; RCT: randomized controlled trial; SE: standard error.

### Randomized Controlled Trials

The Alpha-Stim Anxiety Insomnia and Depression (AID) device was evaluated in the multicenter, double-blind Alpha-Stim-D RCT.<sup>10,11</sup> Patients with moderate to severe major depression received 8 weeks of once daily treatment with Alpha-Stim AID or a sham device. Patients without recent/prior antidepressant use were eligible, although only about 15% of patients had not used antidepressants in the prior 3 months. At week 16, the primary endpoint (the 17-item Hamilton Depression Rating Scale) had decreased by a mean of 5.9 points with Alpha-Stim AID and 6.5 points with the sham device (difference, -0.6; 95% CI, -1.0 to 2.2;  $p=.46$ ). The decreases in both groups were clinically important, but the difference between groups was not significant. Adverse events and tolerability were similar between groups. It is unclear whether patients in the sham device group were allowed to use concurrent antidepressants or behavioral therapy.

Kim et al (2021) reported on a 3-week randomized, double-blind, sham-controlled trial evaluating the effectiveness of home-based CES ( $n=25$ ) versus sham treatment ( $n=29$ ) in nonclinical patients with daily anxiety.<sup>12</sup> Novel, headphone-like, in-ear electrodes were used in this study. Results demonstrated a significant reduction in anxiety scores using the State Anxiety Inventory (SAI) with CES versus sham stimulation treatment. Depression inventory scores did not significantly differ between groups. Limitations of this study included the use of a small sample of nonclinical patients, short follow-up, post-randomization withdrawals that did not contribute data to the analysis, and the unclear clinical significance of a decreased anxiety inventory score.

Barclay and Barclay (2014) reported on a randomized, double-blind, sham-controlled trial evaluating the effectiveness of 1 hour of daily CES for patients with anxiety ( $n=115$ ) and comorbid depression ( $n=23$ ) (Table 6).<sup>13</sup> Analysis of covariance showed a significant advantage of active CES over sham for both anxiety ( $p=.001$ ) and depression ( $p=.001$ ) over 5 weeks of treatment (Table 7). The mean decrease in the Hamilton Rating Scale for Anxiety score was 32.8% for active CES and 9.1% for sham. The mean decrease in the Hamilton Rating Scale for Depression score was 32.9% for active CES and 2.6% for sham. However, because key health outcomes were not addressed and, as noted in a

Veterans Affairs Evidence Synthesis Program review in 2018 by Shekelle et al,<sup>14</sup> due to the serious methodological limitations of this study (i.e., unclear sham credibility), the strength of this evidence is low.

In a smaller, double-blind, sham-controlled randomized trial (N=30), Mischoulon et al (2015) found no significant benefit of CES as adjunctive therapy in patients with treatment-resistant major depression (Tables 6 and 7).<sup>15</sup> Both active and sham groups showed improvements in depression over the 3 weeks of the study, suggesting a strong placebo effect.

In 2015, a sham-controlled, double-blind randomized trial by Lyon et al found no significant benefit of CES with the Alpha-Stim device for symptoms of depression, anxiety, pain, fatigue, and sleep disturbances in women receiving chemotherapy for breast cancer (Tables 6 and 7).<sup>16</sup> This phase 3 trial randomized 167 women with early-stage breast cancer to 1 hour of daily CES or to sham stimulation beginning within 48 hours of the first chemotherapy session and continuing until 2 weeks after chemotherapy ended (range, 6 to 32 weeks). Stimulation intensity was below the level of sensation. Active and sham devices were factory preset, and neither evaluators nor patients were aware of the treatment assignment. Outcomes were measured using validated questionnaires that assessed pain, anxiety, and depression, fatigue, and sleep disturbance. There were no significant differences between the active and sham CES groups during treatment. However, the trial might have been limited by low symptoms levels at baseline, resulting in a floor effect, and the low level of stimulation.

**Table 6. Summary of Randomized Controlled Trial Characteristics Assessing Cranial Electrotherapy Stimulation for Anxiety and Depression**

Study	Country	Sites	Dates	Participants	Interventions	
					Active	Comparator
Barclay et al (2014) <sup>13</sup>	U.S.	1	2012	Patients who met <i>DSM-IV</i> criteria for anxiety disorder as a primary diagnosis	Alpha-Stim self-administered for 1 hour/day for 5 wk (n=60)	Sham Alpha-Stim self-administered for 1 hour/day for 5 wk (n=55)
Mischoulon et al (2015) <sup>15</sup>	U.S.	1	NR	Patients with major depressive disorder with inadequate response to standard antidepressants	<ul style="list-style-type: none"> <li>FW-100</li> <li>1 clinician-supervised and 4 self-administered 1 hour/day for 3 wk (n=17)</li> </ul>	<ul style="list-style-type: none"> <li>Sham FW-100</li> <li>1 clinician-supervised and 4 self-administered for 1 hour/day for 3 wk (n=13)</li> </ul>
Lyon et al (2015) <sup>16</sup>	U.S.	1	2009-2012	Women with newly diagnosed stages I-IIIa breast cancer scheduled for ≥4 cycles of chemotherapy	Alpha-Stim self-administered for 1 hour/day for 2 wk after chemotherapy cessation (n=82)	Sham Alpha-Stim self-administered for 1 hour/day for 2 wk after chemotherapy cessation (n=81)
Kim et al (2021) <sup>12</sup>	Korea	1	NR	Nonclinical volunteers experiencing daily anxiety.	Home-based CES for 3 wk using novel, headphone-like in-ear electrodes delivering an alternating current at a frequency of 10 Hz and an intensity of 500 µA (n=25)	Sham ear devices without flowing current for 3 wk (n=29)
Morriss et al (2023) <sup>11</sup>	England	25	2020-2022	Patients with primary major depression, prior prescription or receipt of antidepressant	Alpha-Stim AID self-administered for 1 hour/day for 8 wks (n=118)	Sham Alpha-Stim AID self-administered for 1 hour/day for 8 wks (n=118)

Study	Country	Sites	Dates	Participants	Interventions
				medication, and a score of 10 to 19 on the 9-item Patient Health Questionnaire	

AID: Anxiety, Insomnia,, and Depression; CES: cranial electrotherapy stimulation; DSM-IV: *Diagnostic and Statistical Manual of Mental Health Disorders, 4th edition*; FW-100: Fisher Wallace Cranial Stimulator; NR: not reported.

**Table 7. Summary of Randomized Controlled Trial Results Assessing Cranial Electrotherapy Stimulation for Anxiety and Depression**

Study			Mean Hamilton Scale for Anxiety Score (SD)			Mean Hamilton Scale for Depression Score (SD)				
			<i>Baseline</i>	<i>Week 1</i>	<i>Week 3</i>	<i>Week 5<sup>a</sup></i>	<i>Baseline</i>	<i>Week 1</i>	<i>Week 3</i>	<i>Week 5<sup>a</sup></i>
Barclay et al (2014) <sup>13</sup> ,										
CES (n=57)			29.5	19.9	16.1	13.4	14.5	9.6	8.1	6.5
Sham (n=51)			27.6	22.0	19.9	20.0	13.2	10.2	9.9	10.0
							<i>Baseline</i>	<i>Week 1</i>	<i>Week 2</i>	<i>Week 3<sup>a</sup></i>
Mischoulon et al (2015) <sup>15</sup> ,										
CES (n=15)							18.1 (1.5)	15.8 (4.2)	14.6 (6.1)	14.8 (6.3)
Sham (n=13)							18.7 (3.9)	14.5 (4.1)	15.3 (5.5)	13.6 (5.8)
			Mean Hospital Anxiety and Depression Scale Score (SD)							
			<i>Anxiety</i>			<i>Depression</i>				
			<i>Timepoint 1</i>	<i>Timepoint 2</i>	<i>Timepoint 3<sup>b</sup></i>	<i>Timepoint 1</i>	<i>Timepoint 2</i>	<i>Timepoint 3<sup>b</sup></i>		
Lyon et al (2015) <sup>16</sup> ,										
CES (n=82)			7.1 (4.1)	4.4 (3.2)		4.1 (3.5)	3.0 (2.5)	4.2 (3.2)		4.5 (3.4)
Sham (n=81)			7.6 (4.1)	5.0 (3.7)		4.5 (4.0)	3.1 (2.8)	4.0 (3.1)		4.6 (3.7)
	Mean State Anxiety Inventory Score (SD)	Mean Beck Depression Inventory Score (SD)								
	<i>Baseline</i>	<i>Week 3<sup>c</sup></i>	<i>Baseline</i>	<i>Week 3<sup>b</sup></i>						
Kim et al (2021) <sup>12</sup> ,										
CES (n=25)	39.1 (4.3)	36.3 (5.9)	16.0 (8.5)	9.9 (6.6)						
Sham (n=29)	38.4 (5.8)	38.9 (5.4)	17.8 (7.9)	9.6 (7.9)						
	Mean change from baseline to week 16 in Hamilton Scale for Depression Score (CI)	Response to treatment at 16 weeks	Remission at 16 weeks							
Morriss et al (2023) <sup>11</sup> ,										

Study	Mean Hamilton Scale for Anxiety Score (SD)		Mean Hamilton Scale for Depression Score (SD)
Alpha-Stim AID (n=118)	-5.9 (-7.1 to -4.8)	33%	30%
Sham (n=118)	-6.5 (-7.7 to -5.4)	41%	42%
Difference (95% CI)	-0.6 (-1.0 to 2.2)	--	--
p	.46	.27	.092

CES: cranial electrotherapy stimulation; CI: confidence interval; SD: standard deviation.

<sup>a</sup> p=.001.

<sup>b</sup> p not significant.

<sup>c</sup> p=.039

Tables 8 and 9 summarize the important relevance and design and conduct limitations of the RCTs discussed above.

**Table 8. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Follow-Up <sup>e</sup>
Barclay et al (2014) <sup>13</sup>	1. Intended use population unclear as the population targeted, those suffering from mental health issues, may be more likely to experience a placebo effect from the sham procedure despite blinding			1. Key health outcomes not addressed	
Mischoulon et al (2015) <sup>15</sup>					
Lyon et al (2015) <sup>16</sup>				1. Key health outcomes not addressed because despite the validated questionnaires being used, these are subjective and are subject to bias	
Kim et al (2021) <sup>12</sup>	4. Study population not representative of intended use; international, nonclinical participants	4. Not the intervention of interest; novel device used		5. Clinical significant difference not prespecified	1. Not sufficient duration for benefit 2. Not sufficient duration for harms
Morriss et al (2023) <sup>11</sup>	1. Not all patients had prior antidepressant treatment; unclear whether patients could have received		2. Unclear whether antidepressants were continued during sham treatment		

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Follow-Up <sup>e</sup>
	concurrent cognitive behavioral therapy				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

<sup>b</sup> Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

<sup>c</sup> Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

<sup>d</sup> Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 9. Study Design and Conduct Limitations**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Follow- Up <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
<b>Barclay et al (2014)<sup>13</sup>,</b>						
<b>Mischoulon et al (2015)<sup>15</sup>,</b>		1. Patients were not blinded to treatment assignment				
<b>Lyon et al (2015)<sup>16</sup>,</b>						
<b>Kim et al (2021)<sup>12</sup>,</b>			2. Inadequate handling of missing data; post-randomization withdrawals were excluded from the data analysis		2. Power not calculated for primary outcome	
<b>Morriss et al (2023)<sup>11</sup>,</b>						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

<sup>b</sup> Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

<sup>d</sup> Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

<sup>f</sup> Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

#### **Parkinson Disease**

Shill et al (2011) found no benefit of CES with the Nexalin device for motor or psychological symptoms in a crossover study of 23 patients with early Parkinson disease.<sup>17</sup>

**Smoking Cessation**

Pickworth et al (1997) reported that 5 days of CES was ineffective for reducing withdrawal symptoms or facilitating smoking cessation in a double-blind RCT of 101 cigarette smokers who wanted to stop smoking.<sup>18</sup>

**Tic Disorders**

Wu et al (2020) published a double-blind, randomized, sham-controlled trial of the efficacy and safety of CES as an add-on treatment for tic disorders in 62 children and adolescents who lacked a clinical response to prior treatment of 4 weeks of pharmacotherapy.<sup>19</sup> Cranial electrotherapy stimulation was delivered via the CES Ultra stimulator (American Neuro Fitness LLC) at 500  $\mu$ A-mA and applied for 30 minutes daily on weekdays for 40 days. The sham CES was delivered at lower than 100  $\mu$ A. The study was conducted at a single academic medical center in China. A total of 9 participants (14.5%) discontinued the intervention early and were excluded from the analyses. There was no significant difference between the active CES and sham groups in the change in Yale Global Tic Severity Scale (YGTSS) score (-31.66% vs. 23.96%;  $p=.13$ ).

**Section Summary: Psychiatric, Behavioral, or Neurologic Conditions**

The most direct evidence related to CES for anxiety and depression comes from 5 sham-controlled randomized trials and systematic reviews. One RCT each found a significant benefit with CES for anxiety or depression, but both had important relevance limitations. Additional evidence is needed to permit conclusions about whether CES improves outcomes for individuals with anxiety or depression. The evidence for depression, anxiety, Parkinson disease, smoking cessation, and tic disorders does not support the use of CES.

**Cranial Electrotherapy Stimulation for Functional Constipation****Clinical Context and Therapy Purpose**

The purpose of CES is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medication, biofeedback, and behavior modification in individuals with functional constipation.

The following PICO was used to select literature to inform this review.

***Populations***

The relevant population of interest is individuals with functional constipation.

***Interventions***

The therapy being considered is CES.

***Comparators***

Comparators of interest include medication, biofeedback, and behavior modification. Treatment includes dietary modifications and a maintenance regimen of laxatives.

***Outcomes***

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity. While studies described below have varying lengths of follow-up, longer follow-up is necessary to fully observe outcomes.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

Gong et al (2016) reported on a single-center, unblinded RCT comparing CES (Alpha-Stim) with biofeedback in 74 subjects with functional constipation.<sup>20</sup> Eligible patients met Rome III criteria for functional constipation and had been recommended by their physicians for biofeedback therapy. Patients were randomized to biofeedback with CES (n=38) or biofeedback alone (n=36) and followed at 4 time points (baseline and 3 follow-up visits); however, the duration of time between each follow-up visit was not specified. In a repeated-measures analysis of variance model for change from baseline, at the second and third follow-up visits, there were significant differences between groups in: Self-Rating Anxiety Scale score (41.8 for CES patients vs. 46.8 for controls;  $p<.001$ ); Self-Rating Depression Scale score (43.08 for CES patients vs. 48.8 for controls;  $p<.001$ ) and the Wexner Constipation Score (10.0 for CES patients vs. 12.6 for controls;  $p<.001$ ). A subset of patients underwent anorectal manometry, with no between-group differences in pressure before or after treatment.

### Section Summary: Functional Constipation

One RCT was identified evaluating CES for functional constipation. Although this trial demonstrated improvements in several self-reported outcomes, given its unblinded design, there was a high risk of bias. Additional confirmation with stronger studies is needed.

### Auricular Electrostimulation for Acute or Chronic Pain

#### Clinical Context and Therapy Purpose

The purpose of auricular electrostimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management and other conservative therapies, in individuals with acute or chronic pain.

The following PICO was used to select literature to inform this review.

#### *Populations*

The relevant population of interest is individuals with acute or chronic pain.

#### *Interventions*

The therapy being considered is auricular electrostimulation.

#### *Comparators*

Comparators of interest include medical management and other conservative therapies. Treatments include physical exercise, stress management, and analgesic and narcotic medication therapy.

#### *Outcomes*

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity. While studies described below have varying lengths of follow-up, longer follow-up is necessary to fully observe outcomes.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

## **Review of Evidence**

### **Acute Pain**

In a 2007 review, Sator-Katzenschlager and Michalek-Sauberer found inconsistent results from studies assessing P-Stim use for the treatment of acute pain (e.g., oocyte aspiration, molar tooth extraction).<sup>21</sup>

An RCT by Holzer et al (2011) tested the efficacy of the P-Stim on 40 women undergoing gynecologic surgery.<sup>22</sup> Patients were randomized to auricular acupuncture or sham stimulation. Patients in the control group received electrodes without needles, and the P-Stim devices were applied without electrical stimulation. The P-Stim device was placed behind the ear at the end of surgery on all patients while they were still under general anesthesia, and the dominant ear was completely covered with identical dressing in both groups to maintain blinding. Postoperatively, patients received paracetamol 1000 mg every 6 hours, with additional piritramide (a parenteral opioid) given on demand. Needles and devices were removed 72 hours postoperatively. A blinded observer found no significant difference between the 2 groups in consumption of piritramide during the first 72 hours postoperatively (acupuncture, 15.3 mg vs. placebo, 13.9 mg) or in visual analog scale (VAS) scores taken at 0, 2, 24, 48, and 72 hours (average VAS score: acupuncture, 2.32 vs. placebo, 2.62).

### **Chronic Low Back Pain**

Sator-Katzenschlager et al (2004) reported on a double-blind RCT that compared auricular electroacupuncture with conventional auricular acupuncture in 61 patients with chronic low back pain (at least 6 months).<sup>23</sup> All needles were connected to the P-Stim device. In the control group, devices were applied without electrical stimulation. Treatment was performed once weekly for 6 weeks, with needles withdrawn 48 hours after insertion. Patients received questionnaires assessing pain intensity and quality, psychological well-being, activity level, and quality of sleep using VAS. There was a significant reduction in pain at up to the 18-week follow-up. Auricular electroacupuncture resulted in greater improvements in the outcome measures than the control procedure. For example, VAS pain intensity was less than 5 in the control group and less than 2 in the electroacupuncture group. This trial was limited by the small number of participants.

### **Chronic Cervical Pain**

Sator-Katzenschlager et al (2003) presented results from a small, double-blind, randomized trial of 21 patients with chronic cervical pain.<sup>24</sup> In 10 patients, needles were stimulated with a P-Stim device, and in 11 patients, no stimulation was administered. Treatment was administered once a week for 6 weeks. Patients receiving electrical stimulation experienced significant reductions in pain scores and improvements in psychological well-being, activity, and sleep.

### **Rheumatoid Arthritis**

Bernateck et al (2008) reported on P-Stim use in an RCT of 44 patients with rheumatoid arthritis.<sup>25</sup> The control group received autogenic training, a psychological intervention in which participants learned to relax their limbs, breathing, and heart rate. Electroacupuncture (continuous stimulation for 48 hours at home) and lessons in autogenic training were performed once weekly for 6 weeks. Also, the control patients were encouraged to use an audiotape to practice autogenic training every day. The needles and devices were removed after 48 hours. Seven patients withdrew from the study before beginning the intervention; the 37 remaining patients completed the trial through the 3-month follow-up. The primary outcome measures were the mean weekly pain intensity and the Disease Activity Score. At the end of treatment and 3-month follow-up, statistically significant improvements were observed in all outcome measures for both groups. There was greater improvement in the electroacupuncture group (VAS pain score, 2.79) than in the control group (VAS pain score, 3.95) during treatment. This level of improvement did not persist at the 3-month follow-up. The clinical significance of a 1-point difference in VAS score from this small trial is unclear.



**Section Summary: Acute or Chronic Pain**

One trial of P-Stim for women undergoing gynecologic surgery found no significant reductions in pain outcomes. Trials in chronic low back pain, chronic cervical pain, and rheumatoid arthritis showed small improvements but had methodologic limitations (e.g., small sample sizes, large loss to follow-up). Additional studies are needed to determine whether auricular electrostimulation improves outcomes for acute or chronic pain.

**Auricular Electrostimulation for Obesity****Clinical Context and Therapy Purpose**

The purpose of auricular electrostimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in individuals with obesity.

The following PICO was used to select literature to inform this review.

***Populations***

The relevant population of interest is individuals with obesity.

***Interventions***

The therapy being considered is auricular electrostimulation.

***Comparators***

Comparators of interest include standard therapy. Treatments include physical exercise, low-carbohydrate dieting, and low-fat dieting.

***Outcomes***

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity. While studies described below have varying lengths of follow-up, longer follow-up is necessary to fully observe outcomes.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

**Review of Evidence****Systematic Reviews**

The results of a systematic review and meta-analysis were published by Kim et al (2018).<sup>26</sup> The purpose of this review was to evaluate the effect of acupuncture and other intervention types on weight loss. In total, 27 RCTs were deemed to meet inclusion criteria. These RCTs had 32 intervention arms and 2219 patients. The meta-analysis results indicate that acupuncture plus lifestyle modification was more effective than lifestyle modification alone (Hedges' g, 1.104; 95% CI, 0.531 to 1.678) and sham acupuncture plus lifestyle modification (Hedges' g, 0.324; 95% CI, 0.177 to 0.471), whereas acupuncture alone was not more effective than sham acupuncture alone and no treatment. Interestingly, acupuncture treatment was effective only in subjects who were overweight (body mass index 25 to <30 kg/m<sup>2</sup>, Hedges' g; 0.528; 95% CI, 0.279 to 0.776), not in subjects with obesity (body mass index ≥30 kg/m<sup>2</sup>). Auricular acupuncture (Hedges' g, 0.522; 95% CI, 0.152 to 0.893), manual acupuncture, (Hedges' g, 0.445; 95% CI, 0.044 to 0.846) and pharmacopuncture (Hedges' g, 0.411; 95% CI, 0.026 to 0.796) also were aligned with weight loss. The authors noted significant heterogeneity across studies with respect to the interventions used, participants, and treatment period.

A systematic review was published by Yeh et al (2017), which included the RCTs by Schukro et al (2014) and Yeh et al (2015) that are summarized in the section below.<sup>27</sup> Although their meta-analysis of 13 RCTs with a total of 1775 participants found that auricular acupoint stimulation improves physical anthropometric parameters, including body weight (mean difference, -1.21 kg; 95% CI, -1.94 to -0.47;  $I^2=88\%$ ), body mass index (mean difference, -0.57 kg/m<sup>2</sup>; 95% CI, -0.82 to -0.33;  $I^2=78\%$ ), body fat (mean difference, -0.83%; 95% CI, -1.43 to -0.24;  $I^2=0\%$ ), and waist circumference (mean difference, -1.75 cm; 95% CI, -2.95 to -0.55;  $I^2=87\%$ ) in overweight and obese adults, key limitations of these findings include high heterogeneity for most of the measures and unclear clinical importance of the differences. Although subgroup analyses based on treatment length (shorter [ $<6$  weeks] vs. longer [ $\geq 6$  weeks]) improved consistency of findings somewhat for the longer subgroup, heterogeneity was still moderate (e.g.,  $I^2=59\%$  for body weight;  $I^2=52\%$  for body mass index).

### Randomized Controlled Trials

Schukro et al (2014) reported on a double-blind RCT evaluating the effects of the P-Stim on weight loss in 56 patients with obesity.<sup>28</sup> The auricular acupuncture points for hunger, stomach, and colon were stimulated 4 days a week over 6 weeks with the P-Stim in the active group (n=28), and the placebo group received treatment with a sham P-Stim device (n=28). At the end of treatment, body weight was reduced by 3.7% in the active stimulation group and 0.7% in the sham group ( $p<.001$ ). Four weeks after treatment, body weight was reduced by 5.1% in the active stimulation group and 0.2% in the sham group ( $p<.001$ ). Similar improvements were observed for body mass index and body fat.

Yeh et al (2015) randomized 70 patients to electrical stimulation on true acupressure points or sham acupressure points.<sup>29</sup> As part of the 10-week treatment program, all patients received auricular acupressure and nutrition counseling following the electrical stimulation sessions. Both groups experienced significant improvements in body mass index, blood pressure, and cholesterol levels from baseline. However, there was no significant difference between groups.

### Section Summary: Obesity

Randomized controlled trials and systematic reviews that have assessed the use of auricular electrostimulation to treat obesity have had small sample sizes, evaluated different treatment protocols, and have reported inconsistent results.

## Auricular Electrostimulation for Opioid Withdrawal Symptoms

### Clinical Context and Therapy Purpose

The purpose of auricular electrostimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy in individuals with opioid withdrawal symptoms.

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with opioid withdrawal symptoms.

### *Interventions*

The therapy being considered is auricular electrostimulation.

### *Comparators*

Comparators of interest include standard therapy. Treatment includes opioid analgesics.

### *Outcomes*

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity. While studies described below have varying lengths of follow-up, longer follow-up is necessary to fully observe outcomes.

## Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Observational Studies

Kroening and Oleson (1985) published a case series assessing 14 patients with chronic pain who were scheduled for withdrawal from their opiate medications.<sup>30</sup> During the withdrawal process, patients were given oral methadone, followed by bilateral auricular electroacupuncture for 2 to 6 hours, and periodic intravenous injections of low dose naloxone. On successive days, the methadone doses were halved. By day 7, 12 of 14 patients were completely withdrawn from methadone. Through at least 1-year follow-up, the 12 patients experienced minimal or no withdrawal symptoms and remained off narcotic medications.

Miranda and Taca (2018) conducted an open-label, uncontrolled, retrospective pilot study to evaluate the effect of neuromodulation with percutaneous electrical field stimulation on opioid withdrawal symptoms.<sup>31</sup> Eight participating clinics provided data on 73 patients who met *Diagnostic and Statistical Manual of Mental Health Disorders, 4th edition*, criteria for opioid dependence and voluntarily agreed to be treated with the NSS-2 Bridge device. All providers were trained to use the device through online modules. Patients were monitored during the first hour following implantation of the device and sent home with instructions to return for follow-up within 1 to 5 days, depending on the clinic, and to keep the device on for the entire 5-day period. The primary outcome of withdrawal symptom improvement was measured using the Clinical Opioid Withdrawal Scale (COWS), which ranges from 0 to 48 (5 to 12=mild, 13 to 24=moderate, 25 to 36=moderately severe, >36=severe). Another outcome was a successful transition, defined as receiving first maintenance medication on day 5 of the study. The mean baseline COWS score was 20.1. At 20 minutes, the mean COWS score decreased to 7.5; at 30 minutes, the mean COWS score was 4.0; and at 60 minutes, the mean COWS score was 3.1. At a 5-day follow-up, 89% of patients successfully transitioned to maintenance medication.

### Section Summary: Opioid Withdrawal Symptoms

Evidence on the use of auricular electrostimulation to treat patients with opioid withdrawal symptoms consists of 2 observational studies with different protocols. Both studies reported successful alleviation of opioid withdrawal symptoms, though, without comparators, conclusions that can be drawn from this evidence are limited.

### 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.

## 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 10 provides a summary of ongoing and unpublished trials that may influence this review.

**Table 10. 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
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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## Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	0783T	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
	63650	Percutaneous implantation of neurostimulator electrode array, epidural
	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
	97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
HCPCS	A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
	E0732	Cranial electrotherapy stimulation (CES) system, any type <i>(Code effective 01/01/2024)</i>
	K1002	Cranial electrotherapy stimulation (CES) system, any type <i>(Code deleted effective 01/1/2024)</i>
	L8680	Implantable neurostimulator electrode, each
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month <i>(Code effective 4/1/2023)</i>
	S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/06/2012	BCBSA Medical Policy adoption
01/11/2013	Policy title change from Auricular Electrostimulation without position change Policy amended to include Cranial Electrotherapy Stimulation
10/31/2014	Policy revision without position change
06/01/2016	Policy title change from Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation Policy revision without position change
04/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
08/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
03/01/2020	Coding update
05/01/2020	Annual review. No change to policy statement. Literature review updated.
04/01/2021	Annual review. No change to policy statement. Literature review updated.
05/01/2022	Annual review. No change to policy statement. Policy guidelines and literature updated.
12/01/2022	Coding update.
03/01/2023	Coding update.
04/01/2023	Annual review. No change to policy statement. Literature review updated.
06/01/2023	Coding update.
03/01/2024	Coding update.
04/01/2024	Annual review. No change to policy statement. Literature review updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*



Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<div>Cranial Electrotherapy Stimulation and Auricular Electrostimulation 8.01.58</div> <div>Policy Statement:</div> <div><div>I. Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is considered <b>investigational</b> in all situations.</div><div>II. Electrical stimulation of auricular acupuncture points is considered <b>investigational</b> in all situations.</div></div>	<div>Cranial Electrotherapy Stimulation and Auricular Electrostimulation 8.01.58</div> <div>Policy Statement:</div> <div><div>I. Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is considered <b>investigational</b> in all situations.</div><div>II. Electrical stimulation of auricular acupuncture points is considered <b>investigational</b> in all situations.</div></div>