Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

Description/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, have been developed to 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.

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 U.S. 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 U.S. 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

pre-programmed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

Regulatory Status:

A number of devices for CES have been cleared for marketing by the U.S. Food and Drug Administration'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 1. FDA product code: JXK

Table 1. 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	10/27/23	K230826	Insomnia
Cervella™	Innovative Neurological Devices	3/07/19	K182311	Insomnia, depression, anxiety
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	5/29/09	K090052	Insomnia, depression, anxiety
Elexoma Medic™	Redplane AG	5/21/08	K070412	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness	4/5/07	K062284	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical	10/13/06	K060158	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific	7/21/03	K024377	Insomnia, depression, anxiety

FDA: Food and Drug Administration

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

Table 2. Auricular Electrostimulation Devices Cleared by the US Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
AXUS ES-5 Electro-Acupuncture Device	Lhasa OMS, INC.	2/3/21	K200636	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Drug Relief V1	DyAnsys Inc	11/5/21	K211971	Reduce symptoms of opioid withdrawal
Sparrow Therapy System	Spark Biomedical, Inc.	1/2/21	K201873	Reduce symptoms of opioid withdrawal
Drug Relief	DyAnsys Inc	5/2/18	K173861	Reduce symptoms of opioid withdrawal

Ansistem-Pp	DyAnsys Inc	3/9/17	K170391	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
NSS-2 Bridge	Innovative Health Solutions	2017		Substance use disorders
Stivax System	Biegler Gmbh	5/26/16	K152571	Practice of acupuncture by qualified practitioners as determined by the states
ANSiStim®	DyAnsys Inc	5/15/15	K141168	Practice of acupuncture by qualified practitioners as determined by states
Pantheon Electrostimulator	Pantheon Research	11/7/14	K133980	Practice of acupuncture by qualified practitioners as determined by the states
Electro Auricular Device	Navigant Consulting, Inc.	10/2/14	K140530	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Biegler GMBH	6/27/14	K140788	Practice of acupuncture by qualified practitioners as determined by the states
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	8/16/13	K130768	Practice of acupuncture by qualified practitioners as determined by the states
JiaJian Electro-Acupuncture Stimulators	Wuxi Jiajian Medical Instrument Co., Ltd.	4/11/13	K122812	Practice of acupuncture by qualified practitioners as determined by the states
Multi-Purpose Health Device	UPC Medical Supplies, Inc. DBA United Pacific Co.	8/5/10	K093322	Unknown - Summary not provided
Electro-Acupuncture: Aculife/Model ADOC-01	Inno-Health Technology, Inc.	4/2/10	K091933	Practice of acupuncture by qualified practitioners as determined by the states
e-Pulse®	Medevice Corporation	12/7/09	K091875	Practice of acupuncture by qualified practitioners as determined by states
Model ES-130	Ito Co., Ltd	11/24/08	K081943	Practice of acupuncture by qualified practitioners as determined by states
P-Stim™	Neuroscience Therapy Corp	3/30/06	K050123	Practice of acupuncture by qualified practitioners as determined by the states
Aculife	Inno-Health Technology, Inc.	3/28/06	K051197	Practice of acupuncture by qualified practitioners as determined by the states
AcuStim	S.H.P. Inti. Pty., Ltd	6/12/02	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

Medical Policy Statement

Cranial electrotherapy (also known as cranial electrostimulation therapy or CES) and electrical stimulation of auricular acupuncture points are experimental/investigational. These therapies have not been scientifically demonstrated to be as effective as conventional treatment.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

97139	97813	97814	99070	A4596	E0732
E1399	S8930				

Rationale

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 PICOs were used to select literature to inform this review.

Populations
The relevant populations of interest are individuals with acute or chronic pain.

Interventions
The therapy being considered is cranial electrotherapy stimulation.

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.(2) The literature search, conducted through 1991, identified two trials evaluating CES for the treatment of headache. Pooled analysis of the two trials (n=102) 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.(3) They identified one 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.(4)

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.(5) 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.(6)

Subsequent to the Cochrane review by O'Connell et al (2018) (6) 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.(7) Mean age was 59.43 years. CES was delivered via the Alpha- Stim M Stimulator, which was preset at 01 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 PSYCHIATRIC, BEHAVIORAL, OR NEUROLOGIC CONDITIONS

Clinical Context and Therapy Purpose

The purpose of cranial electrotherapy stimulation 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 PICOs were used to select literature to inform this review.

Populations

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

Interventions

The therapy being considered is cranial electrotherapy stimulation.

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

Systemic Reviews

An older meta-analysis by Klawansky (1995) described in the Headache section above, analyzed 8 trials (n=228 patients) comparing CES with sham for the treatment of anxiety.(2) 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).(8) 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 -0.69standard 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).(9) Anxiety symptoms were significantly reduced with CES versus control (Hedges' g, -0.625; 95% CI, -0.952 to -0.298; p<.001; I2, 78.6%). Depressive symptoms were also reduced in these patients (Hedges' g, -0.648; 95% CI, -1.062 to -0.234; p=.002; I2, 80.31%). The analysis is limited by high variability in the number of sessions (14-126), session duration (10-60 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)[8,]	Ching et al (2022)[9,]
Amr (2013)	●	
Barclay and Barclay (2014)	●	●
Bystritsky (2008)	●	
Chen (2007)	●	●
Gong (2016)	●	●
Kirsch (2019)	●	
Libretto (2015)	●	
Lu (2005)	●	
Mellen and Mackey (2009)	●	
Mellen and Mackey (2008)	●	
MOrriss and Price (2020)	●	
Morrow (2019)	●	
Platoni (2019)	●	
Rickabaugh (2016)	●	
Royal (2020)	●	
Tillisch (2020)	●	
Yennurajalingam (2018)	●	
Do (2021)		●
Wu (2020)		●
Cho (2016)		●
Lyon (2015)		●
Lu (2014)		●
NCT00723008		●
Tan (2011)		●
Cork (2004)		●

Table 4. Systematic Reviews and Meta-Analyses

Study	Dates	Trials	Participants	N (Range)	Duration

Price et al (2021)	NR	5 RCTs; 12 nonrandomized	Patients exhibiting symptoms of depression and/or anxiety and depression.	RCTs: 242; nonrandomized studies: 1173	RCTs: 3 to 8 weeks; nonrandomized studies: 2 to 24 weeks
Ching et al (2022)	To November 2021	11 RCTs	Patients with anxiety disorder defined by DSM-IV, DSM-IV TR, DSM-V, or ICD10	794 (20-136)	NR

DSM: Diagnostic and Statistical Manual or Mental Disorders; DSM-TR: DSM: 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
Price et al (2021)[8],		
Total N	242	1173
Effect	-0.69	-0.43
SE	0.14	0.03
I^2 (p)	0 (.85)	81.66 (NR)
Ching et al (2022)[9],		
Anxiety		
N	692	
Effect	-0.625	
95% CI	-0.952 to -0.298	
p	<.001	
Depression		
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.(10,11) 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.(12) 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 one hour daily of CES for patients with anxiety (n=115) and co-morbid depression (n=23) (see Table 6).(13) Analysis of covariance showed a significant advantage of active CES over sham for both anxiety (p=0.001) and depression (p=0.001) over 5 weeks of treatment (see Table 7). The mean decrease in the Hamilton Rating Scale for Anxiety was 32.8% for active CES versus 9.1% for sham. The mean decrease in the Hamilton Rating Scale for Depression 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,(14) 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 RCT (n=30), Mischoulon et al (2015) found no significant benefit of a CES as an adjunctive therapy in patients with treatment-resistant major depression (see Tables 6 and 7).(15) 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 RCT by Lyon et al (2015) 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 (see Tables 6 and 7).(16) This phase 3 trial randomized 167 women with early stage breast cancer to 1 h daily CES or to sham stimulation beginning within 48 hours of the first chemotherapy session and continuing until 2 weeks after chemotherapy ended (range, 6-32 weeks). Simulation intensity was below the level of sensation. Active and sham devices were factory pre-set, and neither the 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 the low symptom levels at baseline, resulting in a floor effect, and the low level of stimulation.

Table 6. Summary of RCT Characteristics Assessing CES for Anxiety and Depression

Study	Country	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Barclay et al (2014)	U.S.	1	2012	Patients who met *DSM-IV* criteria for anxiety disorder as primary diagnosis	Alpha-Stim self-administered for 1 h/d for 5 wk. (n=60)	Sham Alpha-Stim self-administered for 1 h/d for 5 wk. (n=55)
Mischoulon et al (2015)	U.S.	1	NR	Patients with major depressive disorder with inadequate response to standard antidepressants	· FW-100 · 1 clinician-supervised and 4 self-administered 1 h/d for 3 wk. (n=17)	· Sham FW-100 · 1 clinician-supervised and 4 self-administered for 1 h/d for 3 wk. (n=13)
Lyon et al (2015)	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 h/d for 2 wk. after chemotherapy cessation (n=82)	Sham Alpha-Stim self-administered for 1 h/d for 2 wk. after chemotherapy cessation (n=81)

Kim et al (2021)	Korea	1	NR	Nonclinical volunteers experiencing daily anxiety.	Home-based CES for 3wk 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)	England	25	2020-2022	Patients with primary major depression, prior prescription or receipt of antidepressant medication, and a score of 10 to 19 on the 9-item Patient Health Questionnaire	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)

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

Table 7. Summary of RCT Results Assessing CES for Anxiety and Depression

Study								
	Mean Hamilton Scale for Anxiety Score				***Mean Hamilton Scale for Depression Score***			
	Baseline	*Week 1*	*Week 3*	*Week 5[a]*	*Baseline*	*Week 1*	*Week 3*	*Week 5[a]*
Barclay et al (2014)								
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
					Baseline	*Week 1*	*Week 2*	*Week 3[a]*
Mischoulon et al (2015)								
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							
	Timepoint 1	*Timepoint 2*	*Timepoint 3[b]*		*Timepoint 1*	*Timepoint 2*	*Timepoint 3[b]*	
Lyon et al (2015)								
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				**Mean Beck Depression Inventory Score**			
	Baseline	*Week 3[c]*			*Baseline*	*Week 3[b]*		
Kim et al (2021)								
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	**Response to treatment at 16 weeks**			**Remission at 16 weeks**			

	Scale for Depression Score (CI)		
Morriss et al (2023)			
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.
[a] p=0.001.
[b] p not significant
[c] p=0.039

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 [a]	Intervention [b]	Comparator [c]	Outcomes [d]	Follow-Up [e]
Barclay et al (2014)	1. Intended use population unclear as the population targeted, those suffering from mental health issues, maybe more likely to experience a placebo effect from the sham procedure despite blinding			1. Key health outcomes not addressed	
Mischoulon et al (2015)					
Lyon et al (2015)				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)	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)	1. Not all patients had prior antidepressant treatment; unclear whether patients could have received concurrent		2. Unclear whether antidepressants were continued		

	cognitive behavioral therapy	during sham treatment	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] 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.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] 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.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations

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

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] 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).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] 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.(17)

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.(18)

Tic Disorders

Wu et al (2020) published a double-blind, randomized, sham-controlled trial of the efficacy and safety of CES as an addon treatment for tic disorders in 62 children and adolescents who

lacked a clinical response to prior treatment of 4 weeks of pharmacotherapy.(19) CES was delivered via the CES ultra-stimulator (American Neuro Fitness LLC) at 500 µA-mA and applied for 30 minutes daily on weekdays for 40 days. The sham CES was delivered at lower than 100 µA. 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 acute or chronic pain, 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 cranial electrotherapy stimulation 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 PICOs were used to select literature to inform this review.

Populations
The relevant population of interest are individuals with functional constipation.

Interventions
The therapy being considered is cranial electrotherapy stimulation.

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 a single-center, unblinded RCT comparing CES (Alpha-Stim) with biofeedback in 74 subjects with functional constipation.(20) 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 four-time points (baseline and three 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; $p<0.001$); Self-Rating Depression Scale score (43.08 for CES patients vs 48.8 for controls; $p<0.001$) and the Wexner Constipation Score (10.0 for CES patients vs 12.6 for controls; $p<0.001$). 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 other 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 PICOs were used to select literature to inform this review.

Populations

The relevant population of interest are 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-Suberer (2007) found inconsistent results from studies assessing P-Stim use for the treatment of acute pain (e.g., oocyte aspiration, molar tooth extraction).(21)

An RCT by Holzer et al (2011) tested the efficacy of the P-Stim on 40 women undergoing gynecologic surgery.(22) 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 the 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 electro-acupuncture with conventional auricular acupuncture in 61 patients with chronic low back pain (at least 6 months).(23) 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 six 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 18-week follow-up. Auricular electro-acupuncture resulted in greater improvement in the outcome measures than the control procedure. For example, VAS pain intensity was less than five in the control group and less than two in the electro-acupuncture 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.(24) 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 the 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 a RCT of 44 patients with rheumatoid arthritis.(25) The control group received autogenic training, a psychological intervention in which participants learn to relax their limbs, breathing, and heart. Electro-acupuncture (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 of follow-up. The primary outcome measures were the mean weekly pain intensity and the Disease Activity Score. At the end of treatment and three-month follow-up, a statistically significant improvements were observed in all outcome measures for both groups. There was greater improvement in the electro-acupuncture group (VAS pain score, 2.79) than in the control group (VAS pain 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 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 PICOs were used to select literature to inform this review.

Populations

The relevant population of interest are 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).(26) The purpose of this review was to evaluate the effect of acupuncture and other intervention types on weight loss.(25) 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^2, Hedges' g=0.528, 95% CI, 0.279 to 0.776), not in subjects with obesity (body mass index ≥30). Auricular acupuncture (Hedges' g=0.522, 95% CI, 0.152 to 0.893), manual acupuncture, (Hedges' g=0445, 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.(27) 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^2; 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. [≥ 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-blinded RCT evaluating the effects of P-Stim on weight loss in 56 patients with obestiy.(28) 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<0.001). Four weeks after treatment, body weight was reduced by 5.1% in the active stimulation group and 0.2% in the sham group (p<0.001). 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.(29) 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
RCTs and systemic reviews that have assessed the use of auricular electrostimulation to treat obesity have had small sample sizes and 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 PICOs were used to select literature to inform this review.

Populations
The relevant population of interest are 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.(30) 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.(31) 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.

SUMMARY OF EVIDENCE

Cranial Electrotherapy Stimulation
For individuals who have acute or chronic pain who receive cranial electrotherapy stimulation, 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 (e.g., depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and a systematic review. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Four 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. 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 and chronic pain (e.g., acute pain from surgical procedures, chronic back pain, chronic pain from osteoarthritis, 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 this 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 on 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 case series report positive outcomes for the use of CES to treat opioid withdrawal symptoms. The studies used different treatment protocols and no comparators, limiting conclusions drawn from the results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

CLINICAL INPUT RECEIVED 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, Blue Cross Blue Shield Association received input on auricular electrostimulation from 3 physician specialty societies and 5 academic medical centers while this policy was under review in 2011. There was consensus that auricular electro-stimulation is experimental/investigational.

PRACTICE GUIDELINES AND POSITION STATEMENTS
No guidelines or statements were identified.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Table 10. provides a summary of ongoing trials that may influence this review.

Table 10. 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	December 2020
NCT03896438	Increased Thalamocortical Connectivity in Tdcs-potentiated Generalization of Cognitive Training	90	April 2024
Unpublished			
NCT05384041	Cranial Electrotherapy Stimulation for the Treatment of Major Depressive Disorder in Adults	255	October 2022
NCT03815253	Electro-acupuncture for Central Obesity	168	March 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.
[a] Denotes industry sponsorship.

Government Regulations
National:
There is no national coverage determination.

Local:
There is no local coverage determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Acupuncture
- Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/20/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/12	5/15/12	5/15/12	Joint policy established
9/1/13	6/19/13	6/26/13	Policy updated to mirror BCBSA. Added cranial electrical stimulation to this policy. Policy title changed from “Auricular Electrostimulation” to “Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation.” This policy replaces the JUMP policies, “Auricular Electrostimulation” and “Cranial Electrical Stimulation.”
3/1/15	12/12/14	12/29/14	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
11/1/19	8/20/19		Routine maintenance
11/1/20	8/18/20		Routine maintenance
11/1/21	8/17/21		Routine maintenance
11/1/22	8/16/22		Routine maintenance
11/1/23	8/15/23		Routine maintenance (slp) Vendor managed: Northwood
11/1/24	8/20/24		Routine maintenance (slp) Vendor managed: Northwood K1002 replaced with E0732

Next Review Date: 3rd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CRANIAL ELECTROTHERAPY STIMULATION (CES) AND AURICULAR ELECTROSTIMULATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.