Policy Number	**SUR702.019**
Policy Effective Date	**09/01/2026**

Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
SUR702.018: Dry Needling of Trigger Points for Myofascial Pain

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) **is experimental, investigational and/or unproven** in all situations.

Electrical stimulation of auricular acupuncture points **is considered experimental, investigational and/or unproven** in all situations.

Policy Guidelines

None.

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 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.

Regulatory Status

NOTE: This section is to be used for informational purposes only. Food and Drug Administration (FDA) approval alone is not a basis for coverage.

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 codes: QJQ, JXK, SFW.

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

Device Name	Manufacturer	Date Cleared	510(k)/PMA Number	Indications
Genesis Sleep	Neurofield, Inc.	12/31/2025	K252951	Insomnia

Proliv™Rx System	Neurolief, Ltd.	12/31/2025	P250010	Depression
Flow FL-100	Flow Neuroscience AB	12/08/2025	P230024	Depression
Modius Lean	Neurovalens Limited	10/17/2025	N/A	Weight management
Modius Stress	Neurovalens Limited	03/27/2024	K232253	Generalized anxiety disorder
Modius Sleep	Neurovalens Limited	10/27/2023	K230826	Insomnia
Cervella™	Innovative Neurological Devices	03/07/2019	K182311	Insomnia, depression, anxiety
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	05/29/2009	K090052	Insomnia, depression, anxiety
Elexoma Medic™	Redplane AG	05/21/2008	K070412	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness	04/05/2007	K062284	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical	10/13/2006	K060158	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator- A, Model TESA-1	Kalaco Scientific	07/21/2003	K024377	Insomnia, depression, anxiety

N/A: not available; PMA: premarket approval.

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) Number	Indications
NET Device™	Net Recovery	05/29/2024	K233166	Reduce symptoms of opioid withdrawal

Sparrow Ascent®	Spark Biomedical, Inc.	06/20/2023	K230796	Reduce symptoms of opioid withdrawal
Needle Stimulator	Wuxi Jiajian Medical Instrument	08/27/2021	K202861	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
AXUS ES-5 Electro-Acupuncture Device	Lhasa OMS, Inc.	02/03/2021	K200636	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Drug Relief V1®	DyAnsys, Inc.	11/05/2021	K211971	Reduce symptoms of opioid withdrawal
Sparrow Therapy System	Spark Biomedical, Inc.	01/02/2021	K201873	Reduce symptoms of opioid withdrawal
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[a]	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

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

[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.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a 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 a 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.

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 policy.

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.

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 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. (3) 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. (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. 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 policy.

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.

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. (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 -0.69 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). (9) 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.

Liu et al. (2025) conducted a meta-analysis of 16 RCTs that evaluated CES in patients (N=1148) with primary and secondary depression. (10) Compared to management without CES, CES had a small effect on depression symptoms (Hedges' g, -0.33; 95% CI, -0.46 to -0.20; I^2=37%). The analysis found that CES did not increase the risk of adverse effects compared to management without CES (odds ratio, 0.84; 95% CI, 0.34 to 2.18; I^2=0%), but there was no effect on quality of life.

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

Study	Price et al. (2021) (8)	Ching et al. (2022) (9)	Liu et al. (2025) (10)
Amr et al. (2013)	●		
Barclay and Barclay (2014)	●	●	●
Bystritsky et al. (2008)	●		

Chen et al. (2007)	●	●	
Gong et al. (2016)	●	●	
Kirsch et al. (2019)	●		
Libretto et al. (2015)	●		
Lu et al. (2005)	●		
Mellen and Mackey (2009)	●		
Mellen and Mackey (2008)	●		
Moriss and Price (2020)	●		●
Morrow et al. (2019)	●		
Platoni et al. (2019)	●		
Rickabaugh et al. (2016)	●		
Royal et al. (2020)	●		
Tillisch et al. (2020)	●		
Yennurajalingam et al. (2018)	●		
Do et al. (2021)		●	●
Wu et al. (2020)		●	
Cho et al. (2016)		●	
Lyon et al. (2015)		●	
Lu et al. (2014)		●	
NCT00723008		●	
Tan et al. (2011)		●	
Cork et al. (2004)		●	
Chang et al. (2022)			●
Dastjerdi et al. (2015)			●
Hong and Yoon (2024)			●
Kim et al. (2021)			●
Lee et al. (2023)			●
Lu et al. (2020)			●
McLure et al. (2015)			●
Mischoulon et al. (2015)			●
Ren et al. (2019)			●
Rose et al. (2009)			●
Scherder et al. (2006)			●
Tillisch et al. (2018)			●
Turner et al. (2014)			●

Table 4. Systematic Reviews and Meta-analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Duration

Price et al. (2021) (8)	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) (9)	To November 2021	11 RCTs	Patients with anxiety disorder defined by DSM-IV, DSM-IV TR, DSM-V, or ICD10.	794 (20-137)	NR
Liu et al. (2025) (10)	To October 2024	16 RCTs	Patients with primary or secondary depression.	1148 (16 to 258)	2 to 24 weeks

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

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	
Liu et al. (2025) (10)		
N	1148	

Effect	-0.33	
95% CI	-0.46 to -0.20	
p	.001	

CI: confidence interval; N: number(s); 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. (11, 12) 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. (13) 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). (14) 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., (15) 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). (16) 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). (17) 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.

Gehrman et al. (2024) published the results of a triple-blind RCT that compared an investigational CES device (OAK, Fischer Wallace Labs) to sham treatment in 255 patients with major depressive disorder. (18) At baseline, patients had to have a Beck Depression Inventory (second edition) score between 20 and 63. Each group received treatment for 2 sessions daily (20 minutes each) for 4 weeks. In the intention to treat population, Beck Depression Inventory scores did not improve between baseline and week 2 (the primary endpoint). However, this outcome was significantly improved when only patients with high adherence were considered (p=.005). Beck Depression Inventory scores were significantly improved at weeks 1 (p=.02) and 4 (p=.028). No major safety concerns were reported. A similar study with the same device in patients with anxiety is awaiting publication.

Woodham et al. (2024) conducted a Phase 2, double-blind RCT with the Flow FL-100 device in patients with depression. (19) Patients (N=174) were randomized to the Flow FL-100 device or sham device for 5 sessions/week for 3 weeks, then 3 session/week for 7 weeks, followed by a 10-week open-label phase. The primary outcome (change in Hamilton Depression Rating Scale scores at 10 weeks) was significantly better with the Flow FL-100 device (improvement of 9.41 points) than the sham device (improvement of 7.14 points; p=.012). Clinical response was more common with the Flow FL-100 device (58.3%) than the sham device (37.8%; p=.017) and the same trend was seen with remission (44.9% vs. 21.8%; p=.004). Adverse effects that were significantly more common with Flow FL-100 than sham treatment included skin redness (63.5% vs. 18.5%, respectively; p<.001), skin irritation (6.9% vs. 0%; p=.03), and trouble concentrating (14.1% vs. 3.7%; p=.03).

Carpenter et al. (2025) published the results of a sham-controlled, double-blind RCT (the MOOD study) with the ProlivRx device in patients with depression. (20) At baseline, the mean Hamilton Rating Scale for Depression score was 21.6 in the ProlivRx group and 22.1 in the sham group. At week 8, Hamilton Rating Scale Depression scores (the primary endpoint) had decreased by a least square mean of 8.62 in the ProlivRx group and 6.01 in the sham group (difference, -2.61; 95% CI, -4.79 to -0.43; p=.0196). There was no difference in response rates as measured by Hamilton Rating Scale Depression scores, but the rate of remission was significantly higher in the ProlivRx group (21.3%) versus the sham group (6.0%; p=.0273). The change from baseline in

Montgomery-Asberg Depression Rating Scale scores to week 8 was similar in both groups. After the double-blind phase there was an 8-week open-label phase; efficacy was maintained between weeks 8 and 16. No major safety concerns were reported.

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) (14)	U.S.	1	2012	Patients who met DSM-IV criteria for anxiety disorder as 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) (16)	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 hour/day for 3 wk (n=17)	• Sham FW-100 • 1 clinician-supervised and 4 self-administered 1 hour/day for 3 wk (n=13)
Lyon et al. (2015) (17)	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) (13)	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) (12)	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 wk (n=118)	Sham Alpha-Stim AID self-administered for 1 hour/day for 8 wk (n=118)
Woodham et al. (2024) (19)	U.S. and UK	NR	2022-2023	Patients in a current depressive episode of at least moderate severity, on stable treatment for at least 6 weeks	Flow FL-100 device, self-administered for 30 minutes at least 5 times/day for 3 weeks, then at least 3 times/day for 7 weeks (n=87)	Sham device self-administered for 30 minutes at least 5 times/day for 3 weeks, then at least 3 times/ day for 7 weeks (n=87)
Carpenter et al. (2025) (20)	U.S. and Israel	13	2021-2024	Patients with unipolar depression and stable antidepressant therapy for at least 4 weeks and evidence of treatment resistance	ProlivRx self-administered for 40 minutes twice daily, 5 to 7 days/ week for 8 weeks (n=62)	Sham self-administered for 40 minutes twice daily, 5 to 7 days/ week for 8 weeks (n=62)

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; wk: week(s); n: number; U.S.: United States; UK: United Kingdom.

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

Study					**Mean Hamilton Scale for Anxiety Score (SD)**			
					Base-line	*Week 1*	*Week 3*	*Week 5[a]*
Barclay et al. (2014) (14)								
CES (n=57)					29.5	19.9	16.1	13.4
Sham (n=51)					27.6	22.0	19.9	20.0
					Mean Hospital Anxiety and Depression Scale Score (SD)			
					Anxiety			
					Time-point 1	*Timepoint 2*	*Timepoint 3[b]*	

Lyon et al. (2015) (17)								
CES (n=82)					7.1 (4.1)	4.4 (3.2)	4.1 (3.5)	
Sham (n=81)					7.6 (4.1)	5.0 (3.7)	4.5 (4.0)	
	Mean State Anxiety Inventory Score (SD)		**Mean Beck Depression Inventory Score (SD)**					
	Base-line	*Week 3*[c]	*Baseline*	*Week 3*[b]				
Kim et al. (2021) (13)								
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) (12)								
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				
Woodham et al. (2024) (19)								
	Mean (SD) change from baseline to week 10 in Hamilton Depression Rating Scale scores		**Clinical response at 10 weeks (based on Hamilton Depression Rating Scale scores)**	**Clinical remission at 10 weeks (based on Hamilton Depression Rating Scale scores)**				
Flow FL-100 (n=87)	-9.41 ± 6.25		58.3%	44.9%				

Sham (n=87)	-7.14 ± 6.10	37.8%	21.8%				
Difference (95% CI)	-2.27 (-0.51 to -4.01)	OR: 2.31 (1.17 to 4.55)	OR: 2.93 (1.41 to 6.09)				
p	.012	.017	.004				
Carpenter et al. (2025) (20)							
	Mean change from baseline to week 8 in Hamilton Depression Rating Scale 17 scores	**Mean change from baseline to week 8 in Mont-gomery-Asberg Depression Rating Scale scores**					
ProlivRx (n=47)	-8.62 (-10.30 to -6.93)	-10.18 (-12.74 to -7.62)					
Sham (n=50)	-6.01 (-7.65 to -4.37)	-8.09 (-10.60 to -5.58)					
Difference (95% CI)	-2.61 (-4.79 to -0.43)	-2.09 (-5.46 to 1.28)					
p	.0196	.2203					

CES: cranial electrotherapy stimulation; CI: confidence interval; n: number(s); OR: odds ratio; SD: standard deviation.

[a] p = 0.001

[b] p not significant

[c] p=.039

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

Study	**Mean Hamilton Scale for Depression Score (SD)**			
	Baseline	*Week 1*	*Week 3*	*Week 5[a]*
Barclay et al. (2014) (14)				
CES (n=57)	14.5	9.6	8.1	6.5
Sham (n=51)	13.2	10.2	9.9	10.0
	Baseline	*Week 1*	*Week 2*	*Week 3[a]*
Mischoulon et al. (2015) (16)				
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)			

	Depression		
	Timepoint 1	*Timepoint 2*	*Timepoint 3[b]*
Lyon et al. (2015) (17)			
CES (n=82)	3.0 (2.5)	4.2 (3.2)	4.5 (3.4)
Sham (n=81)	3.1 (2.8)	4.0 (3.1)	4.6 (3.7)

CES: cranial electrotherapy stimulation; n: number(s); SD: standard deviation.

[a] p = 0.001

[b] p not significant

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) (14)	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) (16)					
Lyon et al. (2015) (17)				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) (13)	4. Study population not representative of intended use; international, nonclinical participants	4. Not the intervention of interest; novel device used		5. Clinically significant difference not prespecified	1. Not sufficient duration for benefit 2. Not sufficient duration for harms
Morriss et al. (2023) (12)	1. Not all patients had prior antidepressant treatment; unclear whether patients could have received concurrent cognitive behavioral therapy		2. Unclear whether antidepressants were continued during sham treatment		
Woodham et al. (2024) (19)			2. Unclear whether prior treatments were continued during the study		
Carpenter et al. (2025) (20)	1. Method of determining treatment resistance was study-specific				

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. Clinically significant difference not prespecified; 6. Clinically 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) (14)						
Mischoulon et al. (2015) (16)		1. Patients were not blinded to treatment assignment				
Lyon et al. (2015) (17)						
Kim et al. (2021) (13)			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) (12)						
Woodham et al. (2024) (19)					3. Difference used for power calculation not reported	
Carpenter et al. (2025) (20)					3. Difference used for power calculation not reported	

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. (21)

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. (22)

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. (23) Cranial electrotherapy stimulation 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 7 sham-controlled randomized trials and systematic reviews. One RCT found a significant benefit with CES for anxiety and 3 RCTs found a significant benefit with CES for depression, but all 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 policy.

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.

Gong et al. (2016) reported on a single-center, unblinded RCT comparing CES (Alpha-Stim) with biofeedback in 74 subjects with functional constipation. (24) 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.

Cranial Electrotherapy Stimulation for Obesity

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 obesity.

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

Populations

The relevant population of interest is individuals with obesity.

Interventions

The therapy being considered is CES.

Comparators

Comparators of interest include medication, biofeedback, and behavior modification. 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.

Randomized Controlled Trial

Viirre et al. (2025) conducted a multicenter, double-blind RCT that compared the efficacy of the Modius Lean device to sham treatment in patients with obesity (Table 10). (25) A total of 241 patients were randomized to Modius Lean (n=117) or an identical sham device (n=124); all patients also received a hypocaloric diet and weekly dietary support. At baseline, mean patient weight was 99.73 kg, mean body mass index was 36.36 kg/m^2, mean total body fat was 46.75 kg, and mean visceral adipose tissue was 1.34 kg. Both groups had a 44% compliance rate, which was defined as use for at least 5 hours per week. Results of this trial are presented in Table 11. After 6 months, mean percentage weight loss (the first co-primary outcome) was -2.91 kg with Modius Lean and -2.30 kg with sham (difference, -0.61; 95% CI, -2.00 to 0.79; p=.394). Patients who used the Modius Lean device lost significantly more visceral adipose tissue than patients who used the sham device, (p=.033) but there was no difference in change in total body fat (p=.165). Adverse effects were fairly common (42% Modius Lean vs. 39% sham), but none were severe.

Table 10. Summary of Randomized Controlled Trial Characteristics Assessing Cranial Electrotherapy Stimulation for Obesity

Study		**Virre et al. (2025) (25)**
Countries		United States, United Kingdom
Sites		4
Dates		2019-2022
Participants		Adults with body mass index ≥ 27 kg/m^2
Interventions	*Active*	Electrical vestibular nerve stimulation (Modius Lean device) for 60 minutes/day on at least 5 days/week for 6 months
	Comparator	Sham device for 60 minutes/day on at least 5 days/week for 6 months

Table 11. Summary of Randomized Controlled Trial Results Assessing Cranial Electrotherapy Stimulation for Obesity

Study	**Percent change in weight (least squares mean)**	**Change in visceral adipose tissue (least squares mean)**	**Change in total body fat (least squares mean)**
Virre et al. (2025) (25)	N=241	N=212	N=240
Modius Lean	-2.91	-12.63 kg	-7.07
Sham	-2.30	-4.67 kg	-4.62
Diff (95% CI)	-0.61 (-2.00 to 0.79)	-7.96 (-15.26 to -0.65)	-2.45 (-5.91 to 1.01)
p	.394	.033	.165

CI: confidence interval; Diff: differential.

The purpose of the study limitations tables 12 and 13 is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following

each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 12. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Virre et al. (2025) (25)					

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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 13. Study Design and Conduct Limitations

Study	Virre et al. (2025) (25)
Allocation[a]	
Blinding[b]	
Selective Reporting[c]	
Data Completeness[d]	1. COVID-19 pandemic contributed to high dropout rate (25%)
Power[e]	3. Difference used in power calculation not reported
Statistical[f]	

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; 5. Other.

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

[d] Data Completeness 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); 7. Other.

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Section Summary: Obesity

One RCT was identified that used CES in the management of obesity. The trial did not find a difference in weight loss between CES and a sham device. Additional trials are needed to confirm the efficacy of CES in this population.

Cranial Electrotherapy Stimulation for Insomnia

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 insomnia.

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

Populations

The relevant population of interest is individuals with insomnia.

Interventions

The therapy being considered is CES.

Comparators

Comparators of interest include medication, biofeedback, and behavior modification. Treatments include nonpharmacologic sleep hygiene measures.

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.

Randomized Controlled Trial

Curry et al. (2024) conducted a multicenter, double-blind RCT that compared the efficacy of the Modius Sleep device to sham treatment in patients with moderate to severe insomnia (Table 14). (26) A total of 147 patients were randomized to Modius Sleep (n=73) or an identical sham device (n=74); all patients used their devices for 30 minutes daily on 5 to 7 days per week for 4

weeks. Compliance, which was defined as use for at least 5 sessions per week, was observed in 80.0% of patients in the sham group and 62.3% of patients in the Modius Sleep group. The primary outcome was the change from baseline in Insomnia Severity Index scores at week 4. Table 15 summarizes the results of this trial. In the intent to treat population, Insomnia Severity Index scores decreased by 3.14 points in the sham group and 4.85 points in the Modius Sleep group (p=.010). The number of patients in each group that experienced a clinically meaningful decrease in Insomnia Severity Index scores was not fully disclosed but the authors stated that it was similar between groups (p=.164). Scores on the Pittsburg Sleep Quality Index were not significantly different between active and sham groups (p>.05).

Table 14. Summary of Randomized Controlled Trial Characteristics Assessing Cranial Electrotherapy Stimulation for Insomnia

Study		**Curry et al. (2024) (26)**
Countries		United Kingdom, Hong Kong
Sites		2
Dates		2022-2023
Participants		Adults with moderate to severe insomnia
Interventions	*Active*	Electrical vestibular nerve stimulation (Modius Sleep device) for 30 minutes/day on 5 to 7 days/week for 4 weeks
	Comparator	Sham device for 30 minutes/day on 5 to 7 days/week for 4 weeks

Table 15. Summary of Randomized Controlled Trial Results Assessing Cranial Electrotherapy Stimulation for Insomnia

Study	**Change in Insomnia Severity Index score**	**Change in Pittsburg Sleep Quality Index scores**
Curry et al. (2024) (26)	N=147	N=147
Modius Sleep	-4.85	-2.81
Sham	-3.14	-1.82
p	.010	.118

The purpose of the study limitations tables 16 and 17 is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 16. Study Relevance Limitations

Study	**Population[a]**	**Intervention[b]**	**Comparator[c]**	**Outcomes[d]**	**Duration of Follow-up[e]**
Curry et al. (2024) (26)					

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. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 17. Study Design and Conduct Limitations

Study	Curry et al. (2024) (26)
Allocation[a]	
Blinding[b]	1. About 60% of both groups correctly guessed their treatment assignment
Selective Reporting[c]	
Data Completeness[d]	
Power[e]	3. Not powered for clinically meaningful difference of 6 points on the Insomnia Severity Index
Statistical[f]	

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; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness 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); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Approval of the Genesis Sleep device was based on substantial equivalence to Modius Sleep. (27) No clinical studies with Genesis Sleep were found.

Section Summary: Insomnia

One RCT was identified that used CES in the management of insomnia. The trial found that CES significantly decreased Insomnia Severity Scores at 4 weeks compared to a sham device, but the number of patients that experienced a clinically meaningful change in insomnia scores was similar between groups.

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 policy.

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.

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). (28)

An RCT by Holzer et al. (2011) tested the efficacy of the P-Stim on 40 women undergoing gynecologic surgery. (29) 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).

Ilfeld et al. (2024) conducted a double-blind RCT pilot study with the NSS-2 Bridge device in 30 patients undergoing cholecystectomy and hernia repair. (30) Treatment with the NSS-2 Bridge or sham stimulation was started in the recovery room and continued for 5 days. Median oxycodone consumption over the first 5 postoperative days was 0 mg in both groups (p=.524). Mean pain intensity over the first 5 postoperative days was 0.6 versus 2.6, respectively (p=.041), on an 11-point numeric rating scale. Adverse events included device discontinuation due to electrode site discomfort (n=3) and electrode placement problems (n=3).

Ilfeld et al. (2025) conducted a double-blind RCT pilot study with the NSS-2 Bridge device in 30 patients undergoing primary, unilateral, total knee arthroplasty. (31) Treatment with the NSS-2 Bridge or sham stimulation was started in the recovery room and continued for 5 days. Median oxycodone consumption over the first 5 postoperative days was 4 mg with auricular nerve stimulation versus 13 mg with sham stimulation (p=.039). Mean pain intensity over the first 5 postoperative days was 2.5 versus 4.0, respectively (p=.014), on an 11-point numeric rating scale. No adverse events were reported.

Ilfeld et al. (2025) conducted a double-blind RCT with the NSS-2 Bridge device in 29 patients undergoing total hip arthroplasty. (32) Patients received active stimulation for 5 days or sham therapy. The primary outcome of median pain intensity during the first 5 days following surgery was similar between groups (2.5 vs. 3.0 for active vs. sham, respectively). The median oxycodone dose was lower in the active stimulation group (3.5 mg) than the sham group (9 mg), but the difference did not reach statistical significance (p=.236). The small sample size likely limited study power to find a difference.

Ilfeld et al. (2025) conducted a double-blind RCT with the NSS-2 Bridge device in 30 patients undergoing ambulatory breast surgery. (33) The procedure was expected to result in moderate to severe pain despite receipt of a paravertebral nerve block. Patients received 5 days of auricular neuromodulation or sham stimulation. During the first 5 days, median pain was 0 in patients who received auricular stimulation versus 1.5 in patients who received sham (p=.084). Median oxycodone exposure was 0 mg in both groups (p=.905). These results should be interpreted with caution due to the small sample size.

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). (34) 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. (35) 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. (36) 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

Four small pilot studies with the NSS-2 Bridge device reported lower pain scores than sham stimulation in patients with postsurgical pain, but the differences were not consistently significant. 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 policy.

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.

Systematic Reviews

The results of a systematic review and meta-analysis were published by Kim et al. (2018). (37) 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^2, Hedges' g; 0.528; 95% CI, 0.279 to 0.776), not in subjects with obesity (body mass index ≥30 kg/m^2). 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. (38) 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. longer [≥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. (39) 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. (40) 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 policy.

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.

Randomized Controlled Trial
Greenwald et al. (2025) conducted a single-center RCT with the NET device in patients undergoing rapid opioid discontinuation. (41) The 108 patients were randomized to treatment with an active or sham device for up to 7 days. The primary outcome was the decrease in the Clinical Opioid Withdrawal Scale (COWS) score at 1 hour after the start of stimulation. The COWS score ranges from 0 to 48 (5 to 12=mild, 13 to 24=moderate, 25 to 36=moderately severe, >36=severe). At 1 hour, the COWS score decreased by 11.1 in patients who received active stimulation versus 8.8 in patients who received sham stimulation ($p<.05$). A higher proportion of patients who received active stimulation achieved a clinically meaningful reduction in COWS score (98.1%) than patients who received sham (83.6%; $p=.016$). Opioid use disorder medications were requested in fewer patients who received active stimulation than sham stimulation (26% vs. 49%; $p<.02$). Using the James Blinding Index, the investigators determined that blinding was moderately maintained at 1 hour.

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. (42) 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. (43) 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 COWS score. 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 an RCT and 2 observational studies with different protocols. The RCT found improvement in withdrawal symptoms with auricular stimulation compared to sham stimulation but blinding and the timeline of outcome assessment were limited.

Summary of Evidence

Cranial Electrotherapy Stimulation (CES)

For individuals who have acute or chronic pain who receive cranial electrotherapy stimulation (CES), the evidence includes a number of small sham-controlled randomized trials and pooled analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Systematic reviews of randomized trials evaluated CES for headache and chronic pain. Pooled analyses found marginal benefits for headache with CES and no benefits for chronic pain with CES. A subsequent sham-controlled trial of remotely supervised CES via secure videoconferencing found a significant benefit with CES for pain reduction, but it had important relevance and conduct and design limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have psychiatric, behavioral, or neurologic conditions (e.g., depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Seven randomized controlled trials (RCTs) evaluated CES for depression and anxiety. One RCT found a significant benefit with CES for anxiety and 3 RCTs found a significant benefit with CES for depression, but all had important relevance limitations. Comparisons between these trials cannot be made due to the heterogeneity in study populations and treatment protocols. Studies evaluating CES for Parkinson disease, smoking cessation, and tic disorders do not support the use of CES for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have functional constipation who receive CES, the evidence includes a RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The single RCT reported positive results for the treatment of constipation with CES. However, the trial was unblinded and most outcomes were self-reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have 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.

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

For individuals who have insomnia who receive CES, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The trial found that CES significantly decreased Insomnia Severity Scores at 4 weeks compared to a sham device, but the number of patients that experienced a clinically meaningful change in insomnia scores was not fully described. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Auricular Electrostimulation

For individuals who have acute or chronic pain (e.g., acute pain from surgical procedures, chronic back pain, chronic pain from osteoarthritis or rheumatoid arthritis) who receive auricular electrostimulation, the evidence includes a limited number of trials. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related

morbidity. Studies evaluating the effect of electrostimulation technology on acute pain are inconsistent, and the small amount of evidence on chronic pain has methodologic limitations. For example, a comparison of auricular electrostimulation with manual acupuncture for chronic low back pain did not include a sham control group, and, in a study of rheumatoid arthritis, auricular electrostimulation was compared with autogenic training and resulted in a small improvement in visual analog scale pain scores of unclear clinical significance. Overall, the few published studies have small sample sizes and methodologic limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive auricular electrostimulation, the evidence includes small RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCTs reported inconsistent results and used different treatment protocols. The systematic reviews are limited by high heterogeneity with respect to the interventions used, participants included, treatment period, and outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have opioid withdrawal symptoms who receive auricular electrostimulation, the evidence includes an RCT and 2 observational studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that opioid withdrawal symptoms were lower with active stimulation than sham stimulation, but the study was small and had limited follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

Ongoing and Unpublished Clinical Trials

Table 18 provides a summary of ongoing and unpublished trials that might influence this policy.

Table 18. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT06212609	Optimized and Personalized Trans-cranial Brain Stimulation in Partial Refractory Epilepsies	20	Jan 2027

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	63650, 64555, 97813, 97814, 0783T
HCPCS Codes	A4543, A4596, E0721, E0732, L8680, S8930

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

References

1. U.S. Food & Drug Administration. FDA News Release: FDA grants marketing authorization of the first device for use in helping to reduce the symptoms of opioid withdrawal. Nov 15, 2017. Available at: <https://www.fda.gov> (accessed December 22, 2025).
2. Klawansky S, Yeung A, Berkey C, et al. Meta-analysis of randomized controlled trials of cranial electrostimulation. Efficacy in treating selected psychological and physiological conditions. J Nerv Ment Dis. Jul 1995; 183(7):478-484. PMID 7623022
3. Brønfort G, Nilsson N, Haas M, et al. Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. 2004; (3):CD001878. PMID 15266458
4. Brønfort G, Haas M, Evans RL, et al. WITHDRAWN: Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. Aug 26 2014; 2014(8):CD001878. PMID 25157618
5. O'Connell NE, Wand BM, Marston L, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev. Apr 11 2014; (4):CD008208. PMID 24729198
6. O'Connell NE, Marston L, Spencer S, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev. Mar 16 2018; 3(3):CD008208. PMID 29547226
7. Ahn H, Galle K, Mathis KB, et al. Feasibility and efficacy of remotely supervised cranial electrical stimulation for pain in older adults with knee osteoarthritis: A randomized controlled pilot study. J Clin Neurosci. Jul 2020; 77:128-133. PMID 32402609
8. Price L, Briley J, Haltiwanger S, et al. A meta-analysis of cranial electrotherapy stimulation in the treatment of depression. J Psychiatr Res. Mar 2021; 135:119-134. PMID 33477056
9. Ching PY, Hsu TW, Chen GW, et al. Efficacy and Tolerability of Cranial Electrotherapy Stimulation in the Treatment of Anxiety: A Systemic Review and Meta-Analysis. Front Psychiatry. 2022; 13:899040. PMID 35757229
10. Liu SY, Chen R, Wang CH, et al. Efficacy of cranial electrotherapy stimulation for treating primary and secondary depression in adults: A meta-analysis of randomized controlled trials. J Affect Disord. Aug 01 2025; 382:488-497. PMID 40286924
11. Patel S, Boutry C, Patel P, et al. A randomised controlled trial investigating the clinical and cost-effectiveness of Alpha-Stim AID cranial electrotherapy stimulation (CES) in patients seeking treatment for moderate severity depression in primary care (Alpha-Stim-D Trial). Trials. Apr 04 2022; 23(1):250. PMID 35379314

12. Morriss R, Patel S, Boutry C, et al. Clinical effectiveness of active Alpha-Stim AID versus sham Alpha-Stim AID in major depression in primary care in England (Alpha-Stim-D): a multicentre, parallel group, double-blind, randomised controlled trial. Lancet Psychiatry. Mar 2023; 10(3):172-183. PMID 36724796
13. Kim J, Kim H, Kim DH, et al. Effects of cranial electrotherapy stimulation with novel in-ear electrodes on anxiety and resting-state brain activity: A randomized double-blind placebo-controlled trial. J Affect Disord. Dec 01 2021; 295:856-864. PMID 34706456
14. Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J Affect Disord. Aug 2014; 164:171-177. PMID 24856571
15. Shekelle PG, Cook IA, Miake-Lye IM, et al. Benefits and Harms of Cranial Electrical Stimulation for Chronic Painful Conditions, Depression, Anxiety, and Insomnia: A Systematic Review. Ann Intern Med. Mar 20 2018; 168(6):414-421. PMID 29435567
16. Mischoulon D, De Jong MF, Vitolo OV, et al. Efficacy and safety of a form of cranial electrical stimulation (CES) as an add-on intervention for treatment-resistant major depressive disorder: A three week double blind pilot study. J Psychiatr Res. Nov 2015; 70:98-105. PMID 26424428
17. Lyon D, Kelly D, Walter J, et al. Randomized sham-controlled trial of cranial microcurrent stimulation for symptoms of depression, anxiety, pain, fatigue and sleep disturbances in women receiving chemotherapy for early-stage breast cancer. Springerplus. 2015; 4:369. PMID 26435889
18. Gehrman PR, Bartky EJ, Travers C, et al. A Fully Remote Randomized Trial of Transcranial Alternating Current Stimulation for the Acute Treatment of Major Depressive Disorder. J Clin Psychiatry. Apr 22 2024; 85(2):23m15078. PMID 38696220
19. Woodham RD, Selvaraj S, Lajmi N, et al. Home-based transcranial direct current stimulation treatment for major depressive disorder: a fully remote phase 2 randomized sham-controlled trial. Nat Med. Jan 2025; 31(1):87-95. PMID 39433921
20. Carpenter LL, George MS, Navarro N, et al. A novel home-based, combined occipital and trigeminal afferent stimulation therapy for major depressive disorder: Efficacy and safety results from a double-blind multicenter randomized sham-controlled study. Brain Stimul. 2025; 18(5):1695-1704. PMID 40886913
21. Shill HA, Obradov S, Katsnelson Y, et al. A randomized, double-blind trial of transcranial electrostimulation in early Parkinson's disease. Mov Disord. Jul 2011; 26(8):1477-1480. PMID 21538515
22. Pickworth WB, Fant RV, Butschky MF, et al. Evaluation of cranial electrostimulation therapy on short-term smoking cessation. Biol Psychiatry. Jul 15 1997; 42(2):116-121. PMID 9209728
23. Wu WJ, Wang Y, Cai M, et al. A double-blind, randomized, sham-controlled study of cranial electrotherapy stimulation as an add-on treatment for tic disorders in children and adolescents. Asian J Psychiatr. Jun 2020; 51:101992. PMID 32145674
24. Gong BY, Ma HM, Zang XY, et al. Efficacy of cranial electrotherapy stimulation combined with biofeedback therapy in patients with functional constipation. J Neurogastroenterol Motil. Jul 30 2016; 22(3):497-508. PMID 26932836

25. VIrre E, Sittlington J, Wing D, et al. Non-invasive vestibular nerve stimulation (VeNS) reduces visceral adipose tissue: results of a randomised controlled trial. Sci Rep. Mar 13 2025; 15(1):8753. PMID 40082596
26. Curry G, Cheung T, Zhang SD, et al. Repeated electrical vestibular nerve stimulation (VeNS) reduces severity in moderate to severe insomnia; a randomised, sham-controlled trial; the modius sleep study. Brain Stimul. 2024; 17(4):782-793. PMID 38797370
27. U.S. Food and Drug Administration. Genesis Sleep Device Approval Summary. December 2025. Available at: <https://www.accessdata.fda.gov> (accessed March 13, 2026).
28. Sator-Katzenschlager SM, Michalek-Sauberer A. P-Stim auricular electroacupuncture stimulation device for pain relief. Expert Rev Med Devices. Jan 2007; 4(1):23-32. PMID 17187468
29. Holzer A, Leitgeb U, Spacek A, et al. Auricular acupuncture for postoperative pain after gynecological surgery: a randomized controlled trail. Minerva Anestesiol. Mar 2011; 77(3):298-304. PMID 21441884
30. Ilfeld BM, Abramson WB, Alexander B, et al. Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following cholecystectomy and hernia repair: a randomized, double-masked, sham-controlled pilot study. Reg Anesth Pain Med. Sep 02 2024; 49(9):628-634. PMID 38388014
31. Ilfeld BM, Abramson WB, Alexander B, et al. Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following total knee arthroplasty: a randomized, double-masked, sham-controlled pilot study. Reg Anesth Pain Med. Jan 07 2025; 50(1):26-35. PMID 38388019
32. Ilfeld BM, Said ET, Alexander BS, et al. Pain Management Following Total Hip Arthroplasty With Percutaneous Auricular Stimulation (Neuromodulation): A Randomized, Double-Masked, Sham-Controlled Pilot Study. Cureus. Feb 2025; 17(2):e78920. PMID 40091968
33. Ilfeld BM, Abramson WB, Said ET, et al. Percutaneous auricular neuromodulation to treat pain after ambulatory breast surgery: A randomized, double-masked, sham-controlled pilot study. Can J Pain. 2025; 9(1):2521117. PMID 40657450
34. Sator-Katzenschlager SM, Scharbert G, Kozek-Langenecker SA, et al. The short- and long-term benefit in chronic low back pain through adjuvant electrical versus manual auricular acupuncture. Anesth Analg. May 2004; 98(5):1359-1364, table of contents. PMID 15105215
35. Sator-Katzenschlager SM, Szeles JC, Scharbert G, et al. Electrical stimulation of auricular acupuncture points is more effective than conventional manual auricular acupuncture in chronic cervical pain: a pilot study. Anesth Analg. Nov 2003; 97(5):1469-1473. PMID 14570667
36. Bernateck M, Becker M, Schwake C, et al. Adjuvant auricular electroacupuncture and autogenic training in rheumatoid arthritis: a randomized controlled trial. Auricular acupuncture and autogenic training in rheumatoid arthritis. Forsch Komplementmed. Aug 2008; 15(4):187-193. PMID 18787327
37. Kim SY, Shin IS, Park YJ. Effect of acupuncture and intervention types on weight loss: a systematic review and meta-analysis. Obes Rev. Nov 2018; 19(11):1585-1596. PMID 30180304
38. Yeh TL, Chen HH, Pai TP, et al. The effect of auricular acupoint stimulation in overweight and obese adults: A systematic review and meta-analysis of randomized controlled trials.

Evidence-Based Complementary and Alternative Medicine. 2017; 2017:3080547. PMID 29358964
39. Schukro RP, Heiserer C, Michalek-Sauberer A, et al. The effects of auricular electroacupuncture on obesity in female patients--a prospective randomized placebo-controlled pilot study. Complement Ther Med. Feb 2014; 22(1):21-25. PMID 24559812
40. Yeh ML, Chu NF, Hsu MY, et al. Acupoint stimulation on weight reduction for obesity: A randomized sham-controlled study. West J Nurs Res. Dec 2015; 37(12):1517-1530. PMID 25183702
41. Greenwalk MK, Arfken CL, Winston JR. A randomized, sham-controlled clinical trial to evaluate the NET Device™ for reducing withdrawal symptom severity during opioid discontinuation. Front Psychiatry. 2025; 16:1510428. PMID 40046990
42. Kroening RJ, Oleson TD. Rapid narcotic detoxification in chronic pain patients treated with auricular electroacupuncture and naloxone. Int J Addict. Sep 1985; 20(9):1347-1360. PMID 2867052
43. Miranda A, Taca A. Neuromodulation with percutaneous electrical nerve field stimulation is associated with reduction in signs and symptoms of opioid withdrawal: a multisite, retrospective assessment. Am J Drug Alcohol Abuse. 2018; 44(1):56-63. PMID 28301217

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
09/01/2026	Document updated. Coverage unchanged. References 10, 19-20, 25-27, 32-33 and 41 added; others updated.
06/15/2025	Document updated with literature review. Coverage unchanged. References 17, 24-25 added.
12/15/2024	Document updated with literature review. Coverage unchanged. Reference 11 added.
12/15/2023	Document updated with literature review. Coverage unchanged. References 4, 6, 8-11 added.
04/15/2022	Document updated with literature review. Coverage unchanged. References 1, 5, and 13 added.
04/01/2021	Reviewed. No changes.

08/15/2020	Document updated with literature review. Coverage unchanged. Rationale and references updated. References 6, 9 and 21 added.
02/15/2020	New medical document originating from SUR702.005 Acupuncture. No change in coverage. Cranial electrotherapy stimulation and auricular electrostimulation are considered experimental, investigational and/or unproven.