Policy Statement

Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is considered **investigational** in all situations.

Electrical stimulation of auricular acupuncture points is considered **investigational** in all situations.

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

Policy Guidelines

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

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

The following codes might also be used for auricular stimulation:

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

The following HCPCS code is specific to auricular stimulation:

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

There is a new HCPC for cranial electrotherapy stimulation:

- **K1002**: Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type

Description

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, provide ambulatory auricular electrical stimulation over a period of several days. CES is being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and functional constipation. Auricular electrical stimulation is being evaluated for pain, weight loss, and opioid withdrawal.

Related Policies

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

Benefit Application

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

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

Regulatory Status

A number of devices for CES have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 1992, the Alpha-Stim® CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. Devices cleared since 2000 are summarized in Table 1. FDA product code: JXK.

Table 1. Cranial Electrotherapy Stimulation (CES) Devices Cleared by the US Food and Drug Administration

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

FDA: Food and Drug Administration.

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

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

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
Drug Relief	DyAnsys Inc	05/02/2018	K173861	Reduce symptoms of opioid withdrawal
NSS-2 Bridge	Innovative Health Solutions	2017		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
Bridge Neurostimulation System	Innovative Health Solutions	2014		Practice of acupuncture by qualified practitioners as determined by the states

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
e-Pulse®	Medevice Corporation	12/07/2009	K091875	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
AcuStim	S.H.P. Intl. Pty., Ltd.	06/12/2002	K014273	As an electroacupuncture device

FDA: Food and Drug Administration.

Rationale

Background

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, provide ambulatory auricular electrical stimulation over a period of several days. CES and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, weight loss, and opioid withdrawal.

Interest in CES began in the early 1900s on the theory that weak pulses of electrical current have a calming effect on the central nervous system. The technique was further developed in the 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 three auricular acupuncture points. The P-Stim device connects to 3 inserted acupuncture needles with caps and wires. The device is preprogrammed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

Literature Review

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one 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. RCTs 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 patients with acute or chronic pain.

The question addressed in this evidence review is: Does CES improve the net health outcome in patients with acute or chronic pain?
The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with acute or chronic pain. Patients with acute or chronic pain are actively managed by occupational therapists, physical therapists and primary care providers in an outpatient clinical setting.

Interventions
The therapy being considered is CES.

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

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

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

Review of Evidence
Headache
Klawansky et al. (1995) published a meta-analysis of 14 RCTs comparing CES with sham for the treatment of various psychological and physiological conditions.[2] The literature search, conducted through 1991, identified 2 trials evaluating CES for the treatment of headache. Pooled analysis of the 2 trials (total 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. They identified 1 poor quality, placebo-controlled, randomized trial (N=100) of CES for a migraine or a tension-type headache.[3] Results from the trial showed greater reductions in pain intensity in the CES group than in the placebo group (0.4; 95% CI, 0.0 to 0.8).

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.[4] 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 (-0.24; 95% CI, -0.48 to 0.01) for the treatment for chronic pain.

Subsequent to the Cochrane review by O'Connell et al (2014),[4] 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.[5] Mean age was 59.43 years. CES was delivered via the Alpha-Stim M Stimulator, which was preset at 01 mA at a frequency of 0.5 Hz, and applied for 1 hour daily on weekdays for 2 weeks. The sham electrodes were identical in appearance and placement, but the stimulator did not deliver electrical current. The study was conducted in a single center in Houston. All 30 participants completed the study and were included in the outcome analyses.

For the primary outcome of clinical pain at 2 weeks as assessed by a Numeric Rating Scale, a significantly greater reduction occurred in the active CES group (-17.00 vs. +5.73; p<.01). No patients reported any adverse effects. Important relevancy limitations include lack of assessment of important health outcomes or long-term efficacy. An important conduct and design limitation is that it is unclear how convincing the sham procedure was as it did not involve any feature designed to simulate a tingling sensation and give the patient the feeling of being treated (i.e., subtherapeutic amplitude, initial current slowly turned to zero). Thus, findings may be subject to the placebo effect. This trial was also limited by the small number of participants. These limitations preclude drawing conclusions based on these findings.

Section Summary: Acute or Chronic Pain

Three 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 patients with psychiatric, behavioral, or neurologic conditions.

The question addressed in this evidence review is: Does CES improve the net health outcome in patients with psychiatric, behavioral, or neurological conditions?
The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with psychiatric, behavioral, or neurologic conditions. Patients with psychiatric, behavioral, or neurologic conditions are actively managed by electrophysiologists and primary care providers in an outpatient clinical setting.

Interventions

The therapy being considered is CES.

Comparators

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

Outcomes

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Anxiety and Depression

The Klawansky et al (1995) meta-analysis 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).

A Cochrane review by Kavirajan et al (2014), with a literature search through February 2014, found no high-quality RCTs assessing CES versus sham for the treatment of depression.[6] Several RCTs with sham controls have been subsequently published and are described below.
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) (see Table 3).[7] Analysis of covariance showed a significant advantage of active CES over sham for both anxiety (p=0.001) and depression (p=0.001) over 5 weeks of treatment (see Table 4). 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.,[8] 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 an adjunctive therapy in patients with treatment-resistant major depression (see Tables 3 and 4).[9] 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 (see Tables 3 and 4).[10] 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, 6-32 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 the low symptoms levels at baseline, resulting in a floor effect, and the low level of stimulation.

Table 3. Summary of RCT Characteristics Assessing CES for Anxiety and Depression

Study	Country	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Barclay et al (2014)[7]	U.S.	1	2012	Patients who met *DSM-IV* criteria for anxiety disorder as primary diagnosis	Alpha-Stim self-administered for 1 h/d for 5 wk (n=60)	Sham Alpha-Stim self-administered for 1 h/d for 5 wk (n=55)
Mischoulon et al (2015)[9]	U.S.	1	NR	Patients with major depressive disorder with inadequate response to standard antidepressants	• FW-100 • 1 clinician-supervised and 4 self-administered 1 h/d for 3 wk (n=17)	• Sham FW-100 • 1 clinician-supervised and 4 self-administered for 1 h/d for 3 wk (n=13)
Lyon et al (2015)[10]	U.S.	1	2009-2012	Women with newly diagnosed stages I-IIIA breast cancer scheduled for≥4 cycles of chemotherapy	Alpha-Stim self-administered for 1 h/d for 2 wk after chemotherapy cessation (n=82)	Sham Alpha-Stim self-administered for 1 h/d for 2 wk after chemotherapy cessation (n=81)

BID: twice daily; CES: cranial electrotherapy stimulation; *DSM-IV*: *Diagnostic and Statistical Manual of Mental Health Disorders, 4th edition*; ECT: electroconvulsive therapy; FW-100: Fisher Wallace Cranial Stimulator; NR: not reported;
RCT: randomized controlled trial.

Table 4. Summary of RCT Results Assessing CES for Anxiety and Depression

Study	Mean Hamilton Scale for Anxiety Score (SD)				Mean Hamilton Scale for Depression Score (SD)			
	Baseline	***Week 1***	***Week 3***	***Week 5[a]***	***Baseline***	***Week 1***	***Week 3***	***Week 5[a]***
Barclay et al (2014)[7]								
CES (n=57)	29.5	19.9	16.1	13.4	14.5	9.6	8.1	6.5
Sham (n=51)	27.6	22.0	19.9	20.0	13.2	10.2	9.9	10.0
					Baseline	***Week 1***	***Week 2***	***Week 3[a]***
Mischoulon et al (2015)[9]								
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)							
	Timepoint 1	***Timepoint 2***	***Timepoint 3[b]***		***Timepoint 1***	***Timepoint 2***	***Timepoint 3[b]***	
Lyon et al (2015)[10]								
CES (n=82)	7.1 (4.1)	4.4 (3.2)	4.1 (3.5)		3.0 (2.5)	4.2 (3.2)	4.5 (3.4)	
Sham (n=81)	7.6 (4.1)	5.0 (3.7)	4.5 (4.0)		3.1 (2.8)	4.0 (3.1)	4.6 (3.7)	

CES: cranial electrotherapy stimulation; RCT: randomized controlled trial; SD: standard deviation.
[a] p=0.001.
[b] p not significant.

Tables 5 and 6 summarize the important relevance and design and conduct limitations of the RCTs discussed above.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Barclay et al (2014)[7]	1. Intended use population unclear as the population			1. Key health outcomes not addressed	

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
	targeted, those suffering from mental health issues, may be more likely to experience a placebo effect from the sham procedure despite blinding				
Mischoulon et al (2015)[9]					
Lyon et al (2015)[10]				1. Key health outcomes not addressed because despite the validated questionnaires being used, these are subjective and are subject to bias	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Barclay et al (2014)[7]						
Mischoulon et al (2015)[9]		1. Patients were not blinded to treatment assignment				
Lyon et al (2015)[10]						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
ITT: intention to treat
[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.[11.]

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.[12.]

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.[13.] CES was delivered via the CES ultra stimulator (American Neuro Fitness LLC) at 500 μA-mA and applied for 30 minutes daily on weekdays for 40 days. The sham CES was delivered at lower than 100 μA. The study was conducted at a single academic medical center in China. A total of 9 participants (14.5%) discontinued the intervention early and were excluded from the analyses. There was no significant difference between the active CES and sham groups in the change in Yale Global Tic Severity Scale (YGTSS) score (-31.66% vs 23.96%; p=.13).

Section Summary: Psychiatric, Behavioral, or Neurologic Conditions
The most direct evidence related to CES for anxiety and depression comes from 3 sham-controlled randomized trials and a systematic review. Only 1 RCT found a significant benefit with CES for depression, but it 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 patients with functional constipation.

The question addressed in this evidence review is: Does CES improve the net health outcome in patients with functional constipation?
The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with functional constipation. Patients with functional constipation are actively managed by nutritionists and primary care providers in an outpatient clinical setting.

Interventions
The therapy being considered is CES.

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

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

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

Review of Evidence
Gong et al. (2016) reported on a single-center, unblinded RCT comparing CES (Alpha-Stim) with biofeedback in 74 subjects with functional constipation.[14] 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; $p<0.001$); Self-Rating Depression Scale score (43.08 for CES patients vs. 48.8 for controls; $p<0.001$) and the Wexner Constipation Score (10.0 for CES patients vs. 12.6 for controls; $p<0.001$). A subset of patients underwent anorectal manometry, with no between-group differences in pressure before or after treatment.

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

Auricular Electrostimulation for Acute or Chronic Pain
Clinical Context and Therapy Purpose
The purpose of auricular electrostimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management and other conservative therapies, in patients with acute or chronic pain.

The question addressed in this evidence review is: Does electrical stimulation of auricular acupuncture points improve the net health outcome in patients with acute or chronic pain? The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with acute or chronic pain. Patients with acute or chronic pain are actively managed by occupational therapists, physical therapists and primary care providers in an outpatient clinical setting.

Interventions
The therapy being considered is auricular electrostimulation.

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

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

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

Review of Evidence
Acute Pain
In a 2007 review, Sator-Katzenschlager and Michalek-Sauberer found inconsistent results from studies assessing P-Stim use for the treatment of acute pain (e.g., oocyte aspiration, molar tooth extraction).[15.]

An RCT by Holzer et al. (2011) tested the efficacy of the P-Stim on 40 women undergoing gynecologic surgery.[16.] 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 given on demand. Needles and devices were removed 72 hours postoperatively. A blinded observer found no significant difference between the 2 groups in consumption of piritramide during the first 72 hours postoperatively (acupuncture, 15.3 mg vs. placebo, 13.9 mg) or in visual analog scale (VAS) scores taken at 0, 2, 24, 48, and 72 hours (average VAS score: acupuncture, 2.32 vs. placebo, 2.62).

Chronic Low Back Pain
Sator-Katzenschlager et al. (2004) reported on a double-blind RCT that compared auricular electroacupuncture with conventional auricular acupuncture in 61 patients with chronic low back pain (at least 6 months).[17.] 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.[18.] 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.[19.] The control group received autogenic training, a psychological intervention in which participants learned to relax their limbs, breathing, and heart rate. Electroacupuncture (continuous stimulation for 48 hours at home) and lessons in autogenic training were performed once weekly for 6 weeks. Also, the control patients were encouraged to use an audiotape to practice autogenic training every day. The needles and devices were removed after 48 hours. Seven patients withdrew from the study before beginning the intervention; the 37 remaining patients completed the trial through the 3-month follow-up. The primary outcome measures were the mean weekly pain intensity and the Disease Activity Score. At the end of treatment and 3-month follow-up, statistically significant improvements were observed in all outcome measures for both groups. There was greater improvement in the electroacupuncture group (VAS pain score, 2.79) than in the control group (VAS pain score, 3.95) during treatment. This level of improvement did not persist at the 3-month follow-up. The clinical significance of a 1-point difference in VAS score from this small trial is unclear.

Section Summary: Acute or Chronic Pain

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

Auricular Electrostimulation for Obesity

Clinical Context and Therapy Purpose

The purpose of auricular electrostimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients with obesity. The question addressed in this evidence review is: Does electrical stimulation of auricular acupuncture points improve the net health outcome in patients with obesity?

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

Populations

The relevant population of interest is individuals with obesity. Patients with obesity are actively managed by nutritionists and primary care providers in an outpatient clinical setting.

Interventions

The therapy being considered is auricular electrostimulation.

Comparators

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

Outcomes

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

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
The results of a systematic review and meta-analysis were published by Kim et al. (2018). The purpose of this review was to evaluate the effect of acupuncture and other intervention types on weight loss.[20] 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 = 0.531–1.678) and sham acupuncture plus lifestyle modification (Hedges' g=0.324, 95% CI=0.177–0.471), whereas acupuncture alone, was not more effective than sham acupuncture alone and no treatment. Interestingly, acupuncture treatment was effective only in subjects with overweight (25 ≤ body mass index < 30, Hedges' g=0.528, 95% CI=0.279–0.776), not in subjects with obesity (body mass index ≥30). Auricular acupuncture (Hedges' g=0.522, 95% CI=0.152–0.893), manual acupuncture, (Hedges' g=0445, 95% CI=0.044–0.846) and pharmacopuncture (Hedges' g=0.411, 95% CI=0.026–0.796) also were aligned with weight loss.

Schukro et al. (2014) reported on a double-blinded RCT evaluating the effects of the P-Stim on weight loss in 56 obese patients.[21] The auricular acupuncture points for hunger, stomach, and colon were stimulated 4 days a week over 6 weeks with the P-Stim in the active group (n=28), and the placebo group received treatment with a sham P-Stim device (n=28). At the end of treatment, body weight was reduced by 3.7% in the active stimulation group and 0.7% in the sham group (p<0.001). Four weeks after treatment, body weight was reduced by 5.1% in the active stimulation group and 0.2% in the sham group (p<0.001). Similar improvements were observed for body mass index and body fat.

Yeh et al. (2015) randomized 70 patients to electrical stimulation on true acupressure points or sham acupressure points.[22] As part of the 10-week treatment program, all patients received auricular acupressure and nutrition counselling 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. A systematic review was published by Yeh et al. (2017)[23] that included the RCTs by Schukro et al. (2014) and Yeh et al. (2015). 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 of -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 (-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=less than 6 weeks vs. longer=more than or equal to 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).

Section Summary: Obesity
RCTs and a systematic review 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 patients with opioid withdrawal symptoms.

The question addressed in this evidence review is: Does electrical stimulation of auricular acupuncture points improve the net health outcome in patients with opioid withdrawal?

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

Populations
The relevant population of interest is individuals with opioid withdrawal symptoms. Patients with opioid withdrawal symptoms are actively managed by emergency care providers and primary care providers in an outpatient clinical setting.

Interventions
The therapy being considered is auricular electrostimulation.

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

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

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

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

Review of Evidence
Kroening and Oleson (1985) published a case series assessing 14 patients with chronic pain who were scheduled for withdrawal from their opiate medications.[24] 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.[25] 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 Bridge through online modules. Patients were monitored during the first hour following implantation of the device and sent home with instructions to return for follow-up within 1 to 5 days, depending on the clinic, and to keep the device on for the entire 5-day period. The primary outcome of withdrawal symptom improvement was measured using the Clinical Opioid Withdrawal Scale (COWS), which ranges from 0 to 48 (5 to 12=mild; 13 to 24=moderate, 25 to 36=moderately severe, >36=severe). Another outcome was a successful transition, defined as receiving first maintenance medication on day 5 of the study. Mean baseline COWS score was 20.1. At 20 minutes, mean COWS score decreased to 7.5; at 30 minutes, mean COWS was 4.0; and at 60 minutes, mean COWS was 3.1. At 5-day follow-up, 89% of patients successfully transitioned to maintenance medication.

Section Summary: Opioid Withdrawal Symptoms
Evidence on the use of auricular electrostimulation to treat patients with opioid withdrawal symptoms consists of 2 case series with different protocols. Both studies reported successful

alleviation of opioid withdrawal symptoms, though, without comparators, conclusions to be drawn from this evidence are limited.

Summary of Evidence
Cranial Electrotherapy Stimulation
For individuals who have acute or chronic pain who receive 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. Three trials studied headache and CES, and 6 trials studied chronic pain and CES. Pooled analyses found marginal benefits for a headache with CES and no benefits for chronic pain with CES. A subsequent sham-controlled trial of remotely supervised CES via secure videoconferencing found a significant benefit with CES for pain reduction, but it had important relevance and conduct and design limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have psychiatric, behavioral, or neurologic conditions (e.g., depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and a systematic review. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Four randomized controlled trials (RCTs) evaluated CES for depression and anxiety. Only 1 RCT found a significant benefit with CES for depression, but it had important relevance limitations. Comparisons between these trials cannot be made due to the heterogeneity in study populations and treatment protocols. Studies evaluating CES for Parkinson disease, smoking cessation and tic disorders do not support the use of CES for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

Auricular Electrostimulation
For individuals who have acute 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 1 systematic review. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCTs reported inconsistent results and used different treatment protocols. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have opioid withdrawal symptoms who receive auricular electrostimulation, the evidence includes 2 case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Both case series report positive outcomes for the use of CES to treat opioid withdrawal symptoms. The studies used different treatment protocols and no comparators, limiting conclusions drawn from the results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

In response to requests from Blue Cross Blue Shield Association, input on auricular electrostimulation was received from 3 physician specialty societies and 5 academic medical centers in 2011. There was a consensus that auricular electrostimulation is investigational.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Table 7 provides a summary of ongoing and unpublished trials that may influence this review.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03825471	Effects of Cranial Electrotherapy Stimulation on Anesthetics Consumption, Perioperative Cytokines Response, and Postoperative Pain in Patients Undergoing Colonic Surgery	80	December 2020
NCT03909217	Effectiveness and Safety of Transcutaneous Electrical Cranial-auricular Acupoint Stimulation (TECAS) for Patients With Mild-to-moderate Depression	470	December 2022
NCT03896438	Increased Thalamocortical Connectivity in Tdcs-potentiated Generalization of Cognitive Training	90	April 2024
NCT04189354	Study of the Synergistic Effects of Biofeedback and Transcranial Electrical Stimulation in Anxio-depressive Disorders	50	November 2021
NCT04061577	Transcranial Electrical Stimulation in Stroke EaRly After Onset Clinical Trial_ Bridging and Adjunctive Neuroprotection	24	September 2022
NCT04171804	Efficacy of Prefrontal Transcranial Direct Current Stimulation On Cognitive Functions and Electrophysiological Measures In Parkinson's Disease Mild Cognitive Impairment	20	May 2020
NCT04160806	The Effect Of Prefrontal Transcranial Direct Current Stimulation On Clinical Severity, Attentional Bias and Interoceptive Accuracy In Panic Disorder	30	November 2020
NCT03222752[a]	A 6-Week Randomized, Double-Blind, Placebo-Controlled Evaluation of Efficacy and Tolerability of Cranial Electrotherapy (CES) for the Treatment of Adults from 18-65 Years of Age with Treatment Resistant Major Depressive Disorder (MDD) with a 2-Week Open Label Extension Phase	141	December 2021
Unpublished			

NCT02851186	Combined Electroacupuncture and Auricular Acupuncture for Postoperative Pain after Abdominal Surgery for Gynecological Diseases: a Randomized Sham-Controlled Trial	72	November 2018
NCT03277846	A Randomized, Double-Blind, Placebo-Controlled Parallel Group Study of the Safety and Efficacy of Nexalin Electrical Brain Stimulation for the Treatment of Depression in Patients Referred to Electro-Convulsive Therapy	101	May 2018
NCT03210155	Effects of Cranial Electrotherapy Stimulation on Psychological Distress and Maternal Functioning in New Mothers During the Postpartum Period	1	Terminated August 2019
NCT03060122	The Clinical Feasibility of Combining Cranial Electrotherapy Stimulation (CES Alpha-Stim) and Non-invasive Interactive Neurostimulation (InterX) for Optimized Rehabilitation Following Extremity Immobilization	35	August 2019

NCT: national clinical trial.
[a] Denotes industry sponsorship.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

Type	Code	Description
CPT®	63650	Percutaneous implantation of neurostimulator electrode array, epidural
	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one
	97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
HCPCS	K1002	Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type
	L8680	Implantable neurostimulator electrode, each
	S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient

Policy History

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

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

Definitions of Decision Determinations

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

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

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

Prior Authorization Requirements (as applicable to your plan)

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

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

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

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