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.

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 no specific code for cranial electrotherapy stimulation. An unlisted code would likely be used.

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 (Electro Medical 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

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

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

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Relief</td>
<td>DyAnsys Inc</td>
<td>05/02/2018</td>
<td>K173861</td>
<td>Reduce symptoms of opioid withdrawal</td>
</tr>
<tr>
<td>NSS-2 Bridge</td>
<td>Innovative Health Solutions</td>
<td>2017</td>
<td></td>
<td>Substance use disorders</td>
</tr>
<tr>
<td>Stivax System</td>
<td>Biegler Gmbh</td>
<td>05/26/2016</td>
<td>K152571</td>
<td>Practice of acupuncture by qualified practitioners as determined by the states</td>
</tr>
<tr>
<td>ANSiStim®</td>
<td>DyAnsys Inc</td>
<td>05/15/2015</td>
<td>K141168</td>
<td>Practice of acupuncture by qualified practitioners as determined by the states</td>
</tr>
<tr>
<td>Bridge Neurostimulation System</td>
<td>Innovative Health Solutions</td>
<td>2014</td>
<td></td>
<td>Practice of acupuncture by qualified practitioners as determined by the states</td>
</tr>
</tbody>
</table>
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 ear lobes. 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.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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, two domains are examined: the relevance and the 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 a powerful tool for evaluating the effectiveness and safety of medical interventions. However, it may not be feasible or ethical to conduct RCTs for all conditions. In such cases, other types of evidence such as case series, case reports, and observational studies may be used to make judgments about the effectiveness and safety of a technology.

Further, the effectiveness and safety of a technology may vary across different subgroups of patients. Therefore, it is important to consider the subgroup analyses when evaluating the evidence. For example, some studies may show that a technology is effective for certain subgroups but not for others. In such cases, the technology may not be recommended for the entire population.

FDA: Food and Drug Administration.
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 Test Purpose**

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

The question addressed in this evidence review is: does cranial electrotherapy stimulation improve the net health outcome in patients with chronic pain?

The following PICOTS were used to select literature to inform this review.

**Patients**

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

**Interventions**

The therapy being considered is cranial electrotherapy stimulation.

**Comparators**

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

**Outcomes**

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity.

**Timing**

The existing literature evaluating cranial electrotherapy stimulation as a treatment for acute or chronic pain has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Patients with acute or chronic pain are actively managed by occupational therapists, physical therapists, and primary care providers in an outpatient clinical setting.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;

c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;

d. 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. 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. 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. 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.

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.

Cranial Electrotherapy Stimulation for Psychiatric, Behavioral, or Neurologic Conditions
Clinical Context and Test Purpose
The purpose of cranial electrotherapy stimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard therapy, in patients with psychiatric, behavioral, or neurologic conditions.

The question addressed in this evidence review is does cranial electrostimulation therapy improve the net health outcome in patients with psychiatric, behavioral, or neurological conditions?

The following PICOTS were used to select literature to inform this review.

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

Interventions
The therapy being considered is cranial electrotherapy stimulation.

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

Outcomes
The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity.

Timing
The existing literature evaluating cranial electrotherapy stimulation as a treatment for psychiatric, behavioral, or neurologic conditions has varying lengths of follow up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Setting
Patients with psychiatric, behavioral, or neurologic conditions are actively managed by electrophysiologists and primary care providers in an outpatient clinical setting.

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

The Klawansky (1995) meta-analysis described in the Headache section above, analyzed 8 trials (n=228 patients) comparing CES with sham for the treatment of anxiety. 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 vs sham for the treatment of depression. 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). 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.

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). Both active and sham groups showed improvements in depression over the 3 weeks of the study, suggesting a strong placebo effect.

A sham-controlled, double-blind randomized trial by Lyon et al (2015) found no significant benefit of CES with the Alpha-Stim device for symptoms of depression, anxiety, pain, fatigue, and sleep disturbances in women receiving chemotherapy for breast cancer (see Tables 3 and 4). This phase 3 trial randomized 167 women with early-stage breast cancer to 1 hour of daily CES or 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 symptom levels at baseline, resulting in a floor effect, and the low level of stimulation.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Active</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barclay et al (2014)5</td>
<td>U.S.</td>
<td>1</td>
<td>2012</td>
<td>Patients who met DSM-IV criteria for anxiety disorder as a primary diagnosis</td>
<td>Alpha-Stim self-administered for 1 h/d for 5 wk (n=60)</td>
<td>Sham Alpha-Stim self-administered for 1 h/d for 5 wk (n=55)</td>
</tr>
<tr>
<td>Mischoulon et al (2015)6</td>
<td>U.S.</td>
<td>1</td>
<td>NR</td>
<td>Patients with major depressive disorder with inadequate response</td>
<td>FW-100 and 4 self-administered and 4 self-supervised</td>
<td>Sham FW-100 and 4 self-administered and 4 self-supervised</td>
</tr>
</tbody>
</table>
Table 4. Summary of RCT Results Assessing CES for Anxiety and Depression

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean Hamilton Scale for Anxiety Score (SD)</th>
<th>Mean Hamilton Scale for Depression Score (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Week 1</td>
</tr>
<tr>
<td>CES (n=57)</td>
<td>29.5</td>
<td>19.9</td>
</tr>
<tr>
<td>Sham (n=51)</td>
<td>27.6</td>
<td>22.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean Hospital Anxiety and Depression Scale Score (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timepoint 1</td>
</tr>
<tr>
<td>CES (n=15)</td>
</tr>
<tr>
<td>Sham (n=13)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barclay et al (2014)</td>
<td>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</td>
<td>1. Key health outcomes not addressed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The purpose of the gap tables (see Tables X and X) is to display notable gaps 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 5. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barclay et al (2014)</td>
<td>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</td>
<td>1. Key health outcomes not addressed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Key health outcomes not addressed because despite the validated questionnaires being
The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- **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.

- **Intervention** key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

- **Comparator** key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

- **Outcomes** key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

- **Follow-Up** key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 6. Study Design and Conduct Gaps**

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocationa</th>
<th>Blindingb</th>
<th>Selective Reportingc</th>
<th>Follow-Upd</th>
<th>Powere</th>
<th>Statisticalf</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barclay et al (2014)5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mischoulon et al (2015)6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lyon et al (2015)7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.8

**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.9

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

The most direct evidence related to CES for anxiety and depression comes from sham-controlled randomized trials. Three trials with this design have reported inconsistent results. Additional evidence is needed to permit conclusions about whether CES improves outcomes for individuals with anxiety or depression. The evidence for acute or chronic pain, Parkinson disease, and smoking cessation does not support the use of CES.
Cranial Electrotherapy Stimulation for Functional Constipation

Clinical Context and Test Purpose
The purpose of cranial electrotherapy stimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medication, biofeedback, and behavior modification in patients with functional constipation.

The question addressed in this evidence review is: does cranial electrostimulation therapy improve the net health outcome in patients with functional constipation?

The following PICOTS were used to select literature to inform this review.

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

Interventions
The therapy being considered is cranial electrotherapy stimulation.

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

Outcomes
The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity.

Timing
The existing literature evaluating cranial electrotherapy stimulation as a treatment for functional constipation has varying lengths of follow up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Setting
Patients with functional constipation are actively managed by nutritionists and primary care providers in an outpatient clinical setting.

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

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. 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. 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 timepoints (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 other studies is needed.

Auricular Electrostimulation For Acute or Chronic Pain

Clinical Context and Test 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 chronic pain?

The following PICOTS were used to select literature to inform this review.

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

Interventions
The therapy being considered is auricular electrostimulation.

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

Outcomes
The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity.

Timing
The existing literature evaluating auricular electrostimulation as a treatment for acute or chronic pain has varying lengths of follow up, ranging from 3-months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 3-months of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients with acute or chronic pain are actively managed by occupational therapists, physical therapists and primary care providers in an outpatient clinical setting.

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

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. 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 review, Sator-Katzenschlager and Michalek-Sauberer (2007) found inconsistent results from studies assessing P-Stim use for the treatment of acute pain (e.g., oocyte aspiration, molar tooth extraction).11

An RCT by Holzer et al (2011) tested the efficacy of the P-Stim on 40 women undergoing gynecologic surgery.12 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).13 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 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.14 In 10 patients, needles were stimulated with a P-Stim device, and in 11 patients, no stimulation was administered. Treatment was administered once a week for 6 weeks. Patients receiving the electrical stimulation experienced significant reductions in pain scores and improvements in psychological well-being, activity, and sleep.

**Rheumatoid Arthritis**

Bernateck et al (2008) reported on P-Stim use in an RCT of 44 patients with rheumatoid arthritis.15 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 everyday. 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 three-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 Test 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 PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with obesity.

Interventions

The therapy being considered is auricular electrostimulation.

Comparators

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

Outcomes

The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity.

Timing

The existing literature evaluating auricular electrostimulation as a treatment for obesity has varying lengths of follow-up. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes.

Setting

Patients with obesity are actively managed by nutritionists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. 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.

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. 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 (LM) was more effective than LM alone (Hedges’ g = 1.104, 95% CI = 0.531-
1.678) and sham acupuncture plus LM (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 = 0.445, 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. 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. As part of the 10-week treatment program, all patients received auricular acupressure and nutrition counseling following the electrical stimulation sessions. Both groups experienced significant improvements in body mass index, blood pressure, and cholesterol levels from baseline. However, there was no significant difference between groups.

Section Summary: Obesity

RCTs that have assessed the use of auricular electrostimulation to treat obesity have had small sample sizes and evaluated different treatment protocols. Additionally, the RCTs reported inconsistent results.

Auricular Electrostimulation for Opioid Withdrawal Symptoms

Clinical Context and Test 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 PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with opioid withdrawal symptoms.

Interventions
The therapy being considered is auricular electrostimulation.

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

Outcomes
The general outcomes of interest are symptoms, morbid events, functional outcomes, and treatment-related morbidity.

Timing
The existing literature evaluating a auricular electrostimulation as a treatment for opioid withdrawal symptoms has varying lengths of follow up, ranging from 1-year. While studies described below all reported at least one outcome of interest, longer follow-up was necessary.
to fully observe outcomes. Therefore, 1-year of follow-up is considered necessary to demonstrate efficacy.

**Setting**

Patients with opioid withdrawal symptoms are actively managed by emergency care providers and primary care providers in an outpatient clinical setting.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;

c. 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.

Kroening and Oleson (1985) published a case series assessing 14 patients with chronic pain who were scheduled for withdrawal from their opiate medications. 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. 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 3 trials studied chronic pain and CES. Pooled analyses found marginal benefits for a headache with CES and no benefits for chronic pain with CES. The evidence is insufficient to determine the effects of the technology on health outcomes.
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. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Three RCTs evaluated CES for depression and anxiety and reported inconsistent outcomes. Comparisons between these trials cannot be made due to the heterogeneity in study populations and treatment protocols. Studies evaluating CES for Parkinson disease and smoking cessation do not support the use of CES for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

**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 the effects of the technology on health outcomes.

For individuals who have obesity who receive auricular electrostimulation, the evidence includes small RCTs. 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

**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 5 provides a summary of ongoing trials that may influence this review.

### Table 7. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NC03222752*a</td>
<td>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</td>
<td>141</td>
<td>Jun 2018</td>
</tr>
<tr>
<td>NC03277846</td>
<td>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</td>
<td>150</td>
<td>Aug 2018</td>
</tr>
<tr>
<td>NC02851186</td>
<td>Combined Electroacupuncture and Auricular Acupuncture for Postoperative Pain after Abdominal Surgery for Gynecological Diseases: a Randomized Sham-Controlled Trial</td>
<td>72</td>
<td>Jan 2019</td>
</tr>
<tr>
<td>NC03210155</td>
<td>Effects of Cranial Electrotherapy Stimulation on Psychological Distress and Maternal Functioning in New Mothers During the Postpartum Period</td>
<td>50</td>
<td>Jan 2020</td>
</tr>
<tr>
<td>NC03060122</td>
<td>The Clinical Feasibility of Combining Cranial Electrotherapy Stimulation (CES Alpha-Stim) and Non-invasive Interactive Neurostimulation (InterX) for Optimized Rehabilitation Following Extremity Immobilization</td>
<td>94</td>
<td>May 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
*a* Denotes industry sponsorship

### References


**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.

IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural</td>
</tr>
<tr>
<td></td>
<td>64555</td>
<td>Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
</tr>
<tr>
<td></td>
<td>97813</td>
<td>Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with patient</td>
</tr>
<tr>
<td></td>
<td>97814</td>
<td>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)</td>
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<tr>
<td>HCPCS</td>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td></td>
<td>S8930</td>
<td>Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient</td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>8E0H300</td>
<td>Acupuncture using Anesthesia</td>
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<tr>
<td></td>
<td>8E0H30Z</td>
<td>Acupuncture</td>
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Policy History

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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/06/2012</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>01/11/2013</td>
<td>Policy title change from Auricular Electrostimulation without position change Policy amended to include Cranial Electrotherapy Stimulation</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>10/31/2014</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>06/01/2016</td>
<td>Policy title change from Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation Policy revision without position change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>04/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>05/01/2018</td>
<td>Policy revision without position change</td>
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<tr>
<td>08/01/2018</td>
<td>Policy revision without position change</td>
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</tr>
<tr>
<td>05/01/2019</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not...
investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

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. Please call (800) 541-6652 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.