Cranial Electrotherapy Stimulation and Auricular Electrostimulation

DISCLAIMER
Our medical policies are designed for informational purposes only and are not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

POLICY
Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is investigational.

Electrical stimulation of auricular acupuncture points is investigational.

POLICY GUIDELINES
There are no CPT codes that are 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: ; 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 neuro-stimulator electrode array, epidural
64555: Percutaneous implantation of neuro-stimulator electrode array; peripheral nerve (excludes sacral nerve)
99070: Supplies and materials (except spectacles), provided by the physician or other qualified health care professional over and above those usually included with the office visit or other services rendered (list drugs, trays, supplies, or materials provided)
L8680: Implantable neuro-stimulator electrode, each.

The following specific HCPCS code for auricular stimulation became effective April 1, 2012:

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

There is no specific code for cranial electrotherapy stimulation. An unlisted code would likely be used.
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, and depression, anxiety, and weight loss.

Interest in CES began in the early 1900s on the theory that weak pulses of electrical current have a calming effect on the central nervous system. The technique was further developed in the U.S.S.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression, and use of CES later spread to Western Europe and the United States as a treatment for various psychological and physiological conditions. Presently, the mechanism of action is thought to be the modulation of activity in brain networks by direct action in the hypothalamus, limbic system, and/or the reticular activating system. One device used in the United States is the Alpha-Stim CES, which provides pulsed, low-intensity current via clip electrodes that attach to the earlobes. Other devices place the electrodes on the eyelids, frontal scalp, mastoid processes, or behind the ears. Treatments may be administered once or twice daily for several days to several weeks.

Other devices provide electrical stimulation to auricular acupuncture sites over several days. One device, the P-Stim, is a single-use miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify 3 auricular acupuncture points. The P-Stim device connects to 3 inserted acupuncture needles with caps and wires. The device is preprogrammed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

REGULATORY STATUS

A number of devices for cranial electrotherapy stimulation 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. FDA-Cleared Devices for Cranial Electrotherapy Stimulation

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Year Cleared</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cranial Electrical Nerve Stimulator</td>
<td>Johari Digital Healthcare (Boranada, India)</td>
<td>2009</td>
<td>Insomnia, depression, anxiety</td>
</tr>
<tr>
<td>Elexoma Medic™</td>
<td>Redplane AG (Zug, Switzerland)</td>
<td>2008</td>
<td>Insomnia, depression, anxiety</td>
</tr>
<tr>
<td>CES Ultra™</td>
<td>Neuro-Fitness (Snoqualmie, WA)</td>
<td>2007</td>
<td>Insomnia, depression, anxiety</td>
</tr>
<tr>
<td>Net-2000 Microcurrent Stimulator</td>
<td>Auri-Stim Medical (Boulder, CO)</td>
<td>2006</td>
<td>Insomnia, depression, anxiety</td>
</tr>
<tr>
<td>Transcranial Electrotherapy</td>
<td>Kalaco Scientific (San Carlos, CA)</td>
<td>2003</td>
<td>Insomnia</td>
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Several devices for electro-acupuncture designed to stimulate auricular acupuncture points have been cleared for marketing through the 510(k) process. Devices cleared since 2000 are summarized in Table 2.

**Table 2: FDA-Cleared Electroacupuncture Devices for Auricular Acupuncture Points**

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Year Cleared</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stivax System</td>
<td>Biegler (Mauerbach, Austria)</td>
<td>2016</td>
<td>Practice of acupuncture by qualified practitioners of acupuncture as determined by the states</td>
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<td>ANSIStim®</td>
<td>DyAnsys (San Mateo, CA)</td>
<td>2015</td>
<td>Practice of acupuncture by qualified practitioners of acupuncture as determined by the states</td>
</tr>
<tr>
<td>EAD (electroauricular device)</td>
<td>Key Electronics (Jeffersonville, IN)</td>
<td>2014</td>
<td>Practice of acupuncture by qualified practitioners of acupuncture as determined by the states</td>
</tr>
<tr>
<td>e-Pulse®</td>
<td>AMM Marketing (Coral Springs, FL)</td>
<td>2009</td>
<td>Practice of acupuncture by qualified practitioners of acupuncture as determined by the states</td>
</tr>
<tr>
<td>P-Stim™</td>
<td>Neuroscience Therapy (Kirkland, WA)</td>
<td>2006</td>
<td>Practice of acupuncture by qualified practitioners of acupuncture as determined by the states</td>
</tr>
<tr>
<td>AcuStim</td>
<td>S.H.P. International (Fullarton, Australia)</td>
<td>2002</td>
<td>As an electroacupuncture device</td>
</tr>
</tbody>
</table>

**RATIONALE**

This evidence review was originally created in September 2011 and has been updated regularly using the MEDLINE database. The most recent literature update was performed through December 22, 2016.

Assessment of efficacy for a therapeutic intervention involves a determination of whether the intervention improves health outcomes compared with available alternatives. The optimal study design for this purpose is a randomized controlled trial (RCT) that compares the therapeutic intervention with existing alternative treatments and includes clinically relevant measures of health outcomes. It is recognized that RCTs are extremely important to assess treatments of pain and functional abilities due to the expected placebo effect and the variable natural history that often responds to conservative care.
In addition, pain and functional ability are subjective outcomes and, thus, may be susceptible to placebo effects. Because of these factors, sham-controlled trials are essential to demonstrate the clinical effectiveness of cranial electrotherapy stimulation (CES) and auricular electrostimulation compared with alternatives (e.g., continued medical management). Therefore, evidence considered for this review focuses on sham-controlled randomized trials and systematic reviews of RCTs.

Cranial Electrotherapy Stimulation

A number of randomized controlled trials and systematic reviews have been published on CES. In 1995, Klawansky et al. published a meta-analysis of 14 randomized trials of CES versus sham. Most of the studies were small, with fewer than 50 patients. Meta-analysis was conducted for the treatment of 4 different psychological and physiological conditions: anxiety (8 trials), brain dysfunction from drug or alcohol use (2 trials), headache (2 trials), and insomnia (2 trials). Meta-analysis showed CES to be significantly more effective than sham for anxiety and headache. Of the 8 studies included in the meta-analysis for anxiety, the sample size was generally small, the populations studied were diverse, and only 2 of the studies independently showed CES to be better than sham treatment. For headache, there was a high risk of bias for 1 of the studies and a poor quality rating for the second according to a Cochrane review (see following). Meta-analysis did not find CES to be more effective than sham for brain dysfunction or insomnia.

Acute or Chronic Pain

Headache

A 2004 Cochrane review of noninvasive treatments for headaches identified 2 poor quality, randomized placebo-controlled trials on CES for migraine or tension-type headache. The trials provided limited evidence that CES is superior to placebo in reducing pain intensity from headache.

Chronic Pain

A 2014 Cochrane review identified 11 randomized trials of CES for chronic pain. Meta-analysis of 6 trials (270 participants) found no significant difference between active and sham stimulation, leading to the conclusion that CES is not effective for the treatment of chronic pain.

Psychiatric, Behavioral or Neurologic Conditions

Anxiety and Depression

A 2014 Cochrane review with a literature search through February 2014 found no high-quality RCTs of CES versus sham for the treatment of depression. Three RCTs with sham controls have been subsequently published.

In 2014, Barclay and Barclay reported a randomized, double-blind, sham-controlled trial of the effectiveness of 1 hour daily of CES in patients with anxiety (n=115) and comorbid depression (n=23). Analysis of covariance showed a significant advantage of active CES over sham for both anxiety (p=0.001) and depression (p=0.001) over the 5 weeks of treatment. The mean decrease in the Hamilton Rating Scale for Anxiety was 32.8% for active CES and 9.1% for sham. The mean decrease in the Hamilton Rating Scale for Depression was 32.9% for active CES and 2.6% for sham.

In contrast, a 2015 sham-controlled, double-blind RCT found no significant benefit of CES with the AlphaStim for symptoms of depression, anxiety, pain, fatigue, and sleep disturbances in women receiving chemotherapy for breast cancer. 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 condition. 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 study may have been limited by the low symptoms levels at baseline, resulting in a floor effect, and the low level of stimulation.

A smaller 2015 double-blind, sham-controlled randomized trial (N=30) found no significant benefit of CES as an adjunctive therapy in patients with treatment-resistant major depression. Both active and sham groups showed improvements in depression over the 3 weeks of the study, suggesting a strong placebo effect.

Roh et al (2016) reported on a sham-controlled randomized trial (N=50) in healthy women with a focus on changes in blood levels of hormones related to the hypothalamic-pituitary axis. However, given that this trial did not include outcomes for individuals with anxiety or depression, it is unclear whether results would be generalizable.

In 1976, Passini et al reported on a randomized trial evaluating anxiety, which was included in the 1995 meta-analysis by Klawansky. Sixty psychiatric patients with various diagnoses (e.g., alcohol addiction, unipolar depression, bipolar disorder, anxiety, schizophrenia, personality disorder) and with either anxiety or depression were included. Thirty-minute treatments on 10 successive workdays resulted in significant improvements in both the CES and the sham groups on self-ratings of anxiety, depression, and hostility, indicating a large placebo effect. Improvements did not differ significantly between groups, but tended to favor the controls not the active CES group.

Subsection Summary: Anxiety and Depression

The most direct evidence related to CES for anxiety and depression comes from sham-controlled randomized trials. Three trials with this design have come to different conclusions. Additional evidence is needed to permit conclusions about whether CES improves outcomes for individuals with anxiety or depression.

Parkinson Disease

Shill et al. 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.

Smoking Cessation

In 1997, Pickworth et al 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 wished to stop smoking.

Functional Constipation

In 2016, Gong et al reported 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 time points (baseline and 3 follow-up visits); however, the duration of time between each follow-up visit does not seem to have been 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 for the following: Self-Rating Anxiety Scale results (for third visit: 41.8 for CES patients vs 46.8 for controls; p<0.001); Self-Rating Depression Scale results (for third visit: 43.08 for CES patients vs 48.8 for controls; p<0.001) and the Wexner Constipation Score results (for third visit: 10.0 for CES patients vs 12.6 for controls; p<0.001). A subset of patients underwent anorectal manometry, and there were no between-group differences before or after treatment.
Section Summary: Functional Constipation
One RCT was identified evaluating CES for functional constipation. Although this trial demonstrated improvements in some self-reported outcomes, given its unblinded design, there was high risk of bias. Additional confirmation with other studies is needed.

Auricular Electrostimulation

Acute or Chronic Pain

Acute Pain
In a 2007 review, Sator-Katzenschlager and Michalek-Sauberer found that studies on P-Stim use in acute pain (e.g., oocyte aspiration, molar tooth extraction) were inconsistent. A 2011 RCT from Europe tested the efficacy of the P-Stim on 40 women undergoing gynecologic surgery. 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 average 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
In 2004, Sator-Katzenschlager et al reported a double-blind RCT that compared auricular electroacupuncture with conventional manual auricular acupuncture in 61 patients with chronic low back pain (at least 6 months). 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 improvement 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. This trial was limited by the small number of participants. In 2003, this group of investigators reported similar effects in a smaller randomized study of 21 patients with chronic cervical pain.

Rheumatoid Arthritis
In a European study, Bernateck et al (2008) reported on P-Stim use in an RCT of 44 patients with rheumatoid arthritis. The control group received autogenic training, a psychological intervention in which participants learned to relax their limbs, breathing, and heart rate. Electro-acupuncture (continuous stimulation for 48 hours at home) and lessons in autogenic training were performed once weekly for 6 weeks. In addition, 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 study 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 at 3-month follow-up, statistically significant improvements were observed in all outcome measures for both groups. There was greater improvement in the electroacupuncture group than in the control group (e.g., VAS pain, 2.79 vs 3.95, respectively) during treatment. This level of improvement did not persist at the 3-month follow-up. The clinical significance of a 1-point difference in VAS from this small trial is unclear.
Section Summary: Acute or Chronic Pain
One trial of P-Stim for women undergoing gynecologic surgery found no significant improvements in pain outcomes. Trials in chronic low back pain and rheumatoid arthritis showed small improvements, but had methodologic limitations. Additional studies are needed to determine whether auricular electrostimulation improves outcomes for acute or chronic pain.

Obesity
The same group of investigators reported in 2014 a double-blinded RCT of 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. At the end of treatment, body weight was reduced by 3.73% in the active stimulation group and 0.70% in the sham group (p<0.001). Four weeks after treatment, body weight was reduced by 5.08% in the active stimulation group and 0.16% in the sham group (p<0.001). Similar changes were observed for body mass index and body fat. Further study by these investigators will include a larger sample size and a longer time of observation.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in January 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

SUMMARY OF EVIDENCE
Cranial Electrotherapy Stimulation
For individuals who have acute or chronic pain, or psychiatric, behavioral, or neurologic conditions (e.g., depression and anxiety, Parkinson disease, schizophrenia, personality disorder, addiction), or functional constipation who receive cranial electrotherapy stimulation, the evidence includes a number of randomized sham-controlled trials, along with several systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. There is a lack of consistent evidence for improvement of health outcomes. The largest body of evidence is for depression and anxiety; for that indication, in 2 of 3 sham-controlled trials, no differences were reported in outcomes between groups. 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) or obesity who receive auricular electrostimulation, the evidence includes a limited number of trials from the same research group. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Studies evaluating the effect of this electrostimulation technology on acute pain are inconsistent, and the small amount of evidence on chronic pain has methodologic limitations. For example, a comparison of auricular electrostimulation with manual acupuncture for chronic low back pain did not include a sham-control group, and, in a study 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.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input
received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input on auricular electrostimulation was received through 3 physician specialty societies and 5 academic medical centers while this policy was under review in 2011. There was consensus that auricular electro-stimulation is 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**REFERENCES:**

8. Roh HT, So WY. Cranial electrotherapy stimulation affects mood state but not levels of peripheral neurotrophic factors or hypothalamic-pituitary-adrenal axis regulation. Technol Health Care. Nov 18 2016. PMID 27886020

CODES

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<th>Description</th>
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<td>HCPCS</td>
<td>S8930</td>
<td>Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient</td>
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<td>ICD-10-CM</td>
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<td>ICD-10-PCS</td>
<td>8E0H300, 8E0H30Z</td>
<td>ICD-10-PCS codes are only used for inpatient services. There is no specific ICD-10-PCS code for this therapy.</td>
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POLICY HISTORY

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<td>02/24/17</td>
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<td>Policy updated with literature review through December 22, 2016; references 8 and 12 added. Policy statements unchanged.</td>
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Original Policy Date: September 2011
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