MEDICAL POLICY – 8.01.58
Cranial Electrotherapy Stimulation and Auricular Electrostimulation

BCBSA Ref. Policy: 8.01.58

Effective Date: May 1, 2019
Last Revised: April 18, 2019
Replaces: N/A

RELATED MEDICAL POLICIES:
1.01.507 Electrical Stimulation Devices
7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Cranial electrotherapy stimulation (CES) provides weak levels of electrical current to the brain. Electrodes are placed on the skull, earlobes, eyelids, or forehead. A small transmitter then sends weak electrical pulses into the brain. It’s believed the current affects particular areas of the brain that play important roles in the body’s hormones and emotions. Another use of CES calls for treating pain by placing the electrodes near the site of pain. Auricular stimulation sends electrical pulses to the acupuncture points of the ear. Both of these systems have been used for depression, anxiety, insomnia (sleeplessness), and weight loss. Because there is not enough medical evidence showing that these technologies improve health, both are considered unproven. A small device worn behind the ear that stimulates specific nerves to try to relieve symptoms of opioid withdrawal is unproven. More research is needed to determine if this device is effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cranial electrotherapy stimulation</td>
<td>Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is investigational in all situations.</td>
</tr>
<tr>
<td>Electrical stimulation</td>
<td>Electrical stimulation of auricular acupuncture points is investigational in all situations.</td>
</tr>
<tr>
<td></td>
<td>Electrical stimulation of the ear (also known as auricular neurostimulation) for opioid withdrawal is investigational.</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>97813</td>
<td>Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>S8930</td>
<td>Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient</td>
</tr>
</tbody>
</table>

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Related Information

N/A
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.

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, 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.

**Summary of Evidence**

*Cranial Electrotherapy Stimulation*

For individuals with 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 5 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 with psychiatric, behavioral, or neurologic conditions (eg, depression and anxiety, Parkinson disease, addiction) who receive CES the evidence includes a number of small sham-controlled randomized trials (RCTs). 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 with 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 with 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.

Ongoing and Unpublished Clinical Trials

Table 1 provides a summary of ongoing trials that may influence this review.
Table 1. 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><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03222752</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>NCT03277846</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>NCT02851186</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>NCT03210155</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>NCT03060122</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

Denotes industry sponsorship

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 from 3 physician specialty societies and 5 academic medical centers while this policy was under review in 2011. There was a consensus that auricular electrostimulation is investigational.
Medicare National Coverage

There is no national coverage determination.

Regulatory Status

A number of devices for CES have been cleared for marketing by the U.S. Food and Drug Administration’s (FDA) 510(k) process (see Table 2). In 1992, the Alpha-Stim® CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. FDA product code: JXK.

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>Year 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>Auri-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 FDA through the 510(k) process. Devices cleared since 2000 are summarized in Table 3. FDA product code: BWK, PZR.
### Table 3: Cranial Electrotherapy Stimulation (CES) Devices Cleared by the US Food and Drug Administration

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Manufacturer</th>
<th>Year Cleared</th>
<th>510(k) No.</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Relief</td>
<td>DyAnsys</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 Gmb</td>
<td>05/26/2016</td>
<td>K152571</td>
<td>Practice of acupuncture by qualified practitioners of acupuncture 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 of acupuncture 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>
<tr>
<td>e-Pulse®</td>
<td>Medevice Corporation</td>
<td>12/07/2009</td>
<td>K091875</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</td>
<td>03/30/2006</td>
<td>K050123</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. Intl. Pty., Ltd.</td>
<td>06/12/2002</td>
<td>K014273</td>
<td>As an electroacupuncture device</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration.

### References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/08/11</td>
<td>New policy; add to Therapy section. Policy created with literature search through April 2011; clinical input reviewed; considered investigational.</td>
</tr>
<tr>
<td>11/13/12</td>
<td>Replace policy. Policy updated with literature review through June 2012, references 1-7 added; cranial electrotherapy stimulation (CES) added as investigational. “Cranial Electrotherapy Stimulation (CES)” added to policy title.</td>
</tr>
<tr>
<td>01/22/13</td>
<td>Update Related Policies. 2.01.50 has been replaced with 2.01.526.</td>
</tr>
<tr>
<td>02/15/13</td>
<td>Update Related Policies. Change title to policy 2.01.526.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. Policy updated with literature review through July 10, 2013; policy statement unchanged.</td>
</tr>
<tr>
<td>10/13/15</td>
<td>Annual Review. Policy updated with literature review through July 6, 2015; no references added. Policy statements unchanged. Related policies updated; 2.01.526 removed.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Policy updated with literature review through December 10, 2015; references 6-7 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>06/01/17</td>
<td>Annual Review, approved May 2, 2017. Policy updated with literature review through December 22, 2016; references 8 and 12 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>10/17/17</td>
<td>Coding update; added CPT code 20974.</td>
</tr>
<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 10, 2018. Policy updated with literature review through April 2018; 17-19 references added. Added electrical stimulation of the ear (also known as auricular neurostimulation) for opioid withdrawal is investigational. Removed CPT code 20974.</td>
</tr>
<tr>
<td>05/01/19</td>
<td>Annual Review, approved April 18, 2019. Policy updated with literature review through January 2019; reference 16 added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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800-722-1471 (TTY: 800-842-5357) لمزيد من المعلومات.

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