MEDICAL POLICY – 8.01.58
Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Related Medical Policies:
1.01.507 Electrical Stimulation Devices
7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Related Medical Policies:

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.

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>Electrotherapy stimulation (cranial)</td>
<td>Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is investigational.</td>
</tr>
<tr>
<td>Electrical stimulation (auricular acupuncture points)</td>
<td>Electrical stimulation of auricular acupuncture points is investigational.</td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (nonoperative)</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><strong>HCPCS</strong></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

Evidence Review
Description

Cranial electrotherapy stimulation, 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. Cranial electrotherapy stimulation and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and weight loss.

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, have been developed to 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 with the theory that weak pulses of electrical current would lead to 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 a variety of 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 Unites 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 a period of several days to several weeks.

Other devices have been developed that 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.

Summary of Evidence

Cranial Electrotherapy Stimulation

For individuals who have acute or chronic pain, or psychiatric, behavioral, or neurologic conditions (eg, 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 (eg, 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 provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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.

Regulatory Status

A number of devices for CES have received marketing clearance through the U.S. Food and Drug Administration’s (FDA) 510(k) process. The Alpha-Stim® CES device (Electromedical Products International) received marketing clearance in 1992 for the treatment of anxiety, insomnia, and depression. 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 Stimulator-A, Model TESA-1</td>
<td>Kalaco Scientific (San Carlos, CA)</td>
<td>2003</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 through the 510(k) process. Devices cleared since 2000 are summarized in Table 2. FDA product code: BWK.

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>
</tr>
<tr>
<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 (electro auricular 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>

FDA: Food and Drug Administration.

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


### History

<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</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>2011</td>
<td>2011: clinical input reviewed; considered investigational.</td>
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<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>
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<tr>
<td>01/22/13</td>
<td>Update Related Policies. 2.01.50 has been replaced with 2.01.526.</td>
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<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>
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<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>
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</table>

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  - Information written in other languages

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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 S09F, HHH Building
  Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
  Complaint forms are available at:

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This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

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يحيى هذا الإشعار معلومات هامة. قد يحيى هذا الإشعار معلومات هامة مخصوصة عليك أو طلب مخصوص. أما Premera Blue Cross فلا تكون هناك تأكدات تمتعك بالعربية التي ترفد الصحف على خلال عملنا. يرجى عقد معلوماتك الخاصة ومساعدتك في هذه الكتابة. قد تكون معلوماتك على بعض المعلومات ومساعدة لكلدن تكون بهذا الإذن. تصل 800-722-1471 (TTY: 800-842-5357).

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Italiano (Italian):

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmong (Hmong):
Tsaab nthaw tshiak xo no muaj cov ntshiab lus tseem ceeb. Tej laam tsab nthaw tshiak xo no muaj cov ntshiab lus tseem ceeb boj kog daim ntawv thov kev pab lus yog kog chov kev pab cuam los nthaw Premera Blue Cross. Tej laam muaj cov hnb tseem ceeb cuam rau hauv daim ntawv no. Tej laam kog juy yuav ta u qee yam peb kom kog ua tis pub dhaav cov cajj nyooj uas teev tsg rau hauv daim ntawv no mas kog juy yuav taia bas kev pab cuam kho moh los yog kev pab them taj se khy kho moh ntawv. Kog muaj cai kom lawv muab cov ntshiab lus no uas tuab muab sau uao kog hom lus pub dawb rau kog. Hu rau 800-722-1471 (TTY: 800-842-5357).

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalab nga adda ket naglaon iti napateg nga impormasion maiyanggep iti aplikasyon noyene coverage babaen iti Premera Blue Cross. Daytoy ket mabalab dagitig importante a pelsa iti daytoy a pakdaar. Mabalab nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw nga amendingo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalaginayo iti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulog iti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga lus 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
This notification may contain important information about your application or coverage. You are entitled to receive this information and assistance in your language without cost. It is possible that there are key dates in this understanding. You may need to act within these dates to avoid losing coverage or paying higher premiums.