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, depression, anxiety, and weight loss.

Related Policies

- Electrical Stimulation for Pain and Other Conditions
- Transcranial Magnetic Stimulation
- Vagus Nerve Stimulation

Policy

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

Electrical stimulation of auricular acupuncture points is considered investigational.

Policy Guidelines

Coding

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

There are no CPT codes specific for electrical stimulation of auricular acupuncture points. The following CPT codes may 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 may also be used for auricular stimulation:

- 63650: Percutaneous implantation of neurostimulator electrode array, epidural
• **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 neurostimulator electrode, each

There is a specific HCPCS code for auricular stimulation:

• **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.

**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)) prohibit 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.

**Rationale**

**Background**

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim®. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim™ and E-pulse, 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, 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 Union of Soviet Socialist Republics 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 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 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.

**Cranial Electrotherapy Stimulation**

A number of randomized controlled trials (RCTs) and systematic reviews have been published on cranial electrotherapy stimulation (CES). In 1995, Klawansky et al published a meta-analysis of 14 randomized trials of CES versus sham.\(^1\) 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).\(^2\) Meta-analysis did not find CES to be more effective than sham for brain dysfunction or insomnia.

**Anxiety and Depression**

The largest randomized study on anxiety that was included in the 1995 systematic review was a 1976 report by Passini et al.\(^3\) Sixty psychiatric patients with a variety of diagnoses (e.g., alcohol addiction, unipolar depression, bi-polar 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 sham groups on self-ratings of anxiety, depression, and hostility, indicating a large placebo effect. Improvements were not significantly different between the groups but tended to favor the controls rather than the active CES group. 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).\(^4\) 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 versus 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.

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.\(^5\)

**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.\(^2\) The trials provided limited evidence that CES is superior to placebo in reducing pain intensity from headache.
Medical Policy

Chronic Pain

A 2010 Cochrane review of noninvasive brain stimulation techniques for chronic pain identified 8 randomized trials (5 parallel study design and 3 crossover design with a total of 391 participants). Chronic pain conditions included osteoarthritis of the hip and knee, chronic back and neck pain, fibromyalgia, and chronic pain following spinal cord injury. Meta-analysis of 3 trials (133 participants) where it was possible to extract data, found no difference between active CES and sham stimulation on pain at short-term follow-up, leading to the conclusion that CES may be ineffective for chronic pain. A 2014 update of the 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, reinforcing the conclusion that CES is not effective for the treatment of chronic pain.

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.

Section Summary

A number of randomized double-blind sham-controlled trials along with several systematic reviews have been conducted on CES for a variety of conditions. In spite of the number of trials, there is a lack of consistent evidence for improvement of health outcomes.

Auricular Electrostimulation

Acute Pain

In a 2007 review, Sator-Katzenschlager and Michalek-Suberer found that studies on the use of the P-Stim in acute pain (e.g., oocyte aspiration and molar tooth extraction) are not consistent. A 2011 randomized trial from Europe tested the efficacy of the P-Stim in 40 female patients undergoing gynecologic surgery. Patients were randomly assigned to receive 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 the operation 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 1000 mg paracetamol 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 vs. placebo: 15.3 mg vs. 13.9 mg, respectively) or on visual analog scale (VAS) scores taken at 0, 2, 24, 48, and 72 hours (average of 2.32 vs. 2.62, acupuncture vs. placebo, respectively).

Chronic Low Back Pain

At the time this policy was created, use of the P-Stim had been reported only in European trials. In 2004, Sator-Katzenschlager et al reported a randomized double-blind controlled study of auricular electro-acupuncture compared 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 improvement in pain at up to 18 week follow-up. Auricular electro-acupuncture resulted in greater improvement in the outcome measures than that of the control group. For example, at 18-week follow-up, VAS pain intensity was less than 5 in the control group and less than 2 in the electro-acupuncture. This study is limited by the small number of participants. In 2003, this group of investigators had reported similar effects in a small randomized study of 21 patients with chronic cervical pain.

Obesity

The same group of investigators reported a randomized double-blinded study 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 for 4 days per week over 6 weeks. At the end of treatment, body weight was reduced by 3.73% in the active stimulation group and .70% in the sham group (p<0.001). From the beginning of treatment to 4 weeks after the end of treatment, body weight was reduced by 5.08% in the active stimulation group and .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.

Rheumatoid Arthritis

In another European study from 2008, Bemateck et al reported the use of the P-Stim device in a RCT of 44 patients with rheumatoid arthritis. The control group received autogenic training, a psychological intervention in which participants learn to relax their limbs, breathing, and heart. 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 3 months of 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, a statistically significant improvement was observed in all outcome measures for both groups. There was greater improvement in the electro-acupuncture group than the control group (e.g., VAS pain 2.79 vs. 3.95) during the treatment period. This difference 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

Studies evaluating the effect of this technology on acute pain are not consistent, 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. In another study, auricular electrostimulation was compared with autogenic training and resulted in a small improvement in VAS pain scores of unclear clinical significance. The positive effect of electrostimulation that was reported for weight loss requires confirmation in a larger sample of patients. The evidence available at this time is insufficient to determine the effect of auricular electrostimulation on health outcomes, including acute and chronic pain and weight loss.
Summary of Evidence

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 the 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, depression, anxiety, and weight loss. The literature on CES consists of a number of randomized controlled trials and systematic reviews, which provide little support for the efficacy of this treatment approach. The literature on auricular electrostimulation is limited in quantity and the available trials are not of high quality. Additional randomized studies with a larger number of subjects are needed to evaluate the efficacy of this treatment approach. Therefore, CES and auricular electrostimulation are considered investigational.

Supplemental Information

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Cranial electrotherapy stimulation and auricular electrostimulation are not preventive services.

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


Documentation Required for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT®</td>
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<td>No specific code</td>
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<tr>
<td>HCPCS</td>
<td>S8930</td>
<td>Electrical stimulation of auricular acupuncture points</td>
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Medical Policy

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<tr>
<th>Procedure</th>
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<th>Description</th>
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<td>ICD-10 Procedure</td>
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<td>Other procedures, integumentary system, percutaneous, acupuncture code list</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.

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<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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<tr>
<td>7/6/2012</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
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<tr>
<td>1/11/2013</td>
<td>Policy title change from Auricular Electrostimulation without position change. Policy amended to include Cranial Electrotherapy Stimulation.</td>
<td>Medical Policy Committee</td>
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<tr>
<td>10/31/2014</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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</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

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

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 also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.