Name of Policy:
Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

Policy #: 021  
Category: DME/Medical  
Latest Review Date: August 2014  
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
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 process, 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.

Interest in cranial electrotherapy stimulation (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 U.S. 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 the brain networks by direct action in the hypothalamus, limbic system and/or the reticular activation system. One device used in the U.S. 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 that have been developed that provider 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 three inserted acupuncture needles with caps and wires. The device is pre-programmed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

Policy:
Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Electrical stimulation of auricular acupuncture points does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.
medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**

**Cranial Electrotherapy Stimulation (CES)**

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 treatment. Most of the studies were small, with fewer than 50 patients. Meta-analysis was conducted for the treatment of four different psychological and physiological conditions: anxiety (eight trials), brain dysfunction from drug or alcohol use (two trials), headache (two trials), and insomnia (two trials). Meta-analysis showed CES to be significantly more effective than sham for anxiety and headache. Of the eight studies included in the meta-analysis for anxiety, the sample size was generally small, the populations studied were diverse, and only two of the studies independently showed CES to be better than sham treatment. For headache, there was a high risk of bias for one of the studies and a poor quality rating for the second according to a Cochran review. 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. 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 ten successive workdays resulted in significant improvement 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 one hour daily of CES in patients with anxiety (n=115) and co-morbid depression (n=23). Analysis of covariance showed a significant advantage of active CES over sham for both anxiety (p=.001) and depression (p=.001) over the five 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 randomized controlled trials of CES versus sham for the treatment of depression.

**Headache**

A 2009 Cochrane review of non-invasive treatments for headaches identified two 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 2010 Cochrane review of non-invasive brain stimulation techniques for chronic pain identified eight randomized trials (five parallel study designs and three cross-over designs 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 three 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 eleven randomized trials of CES for chronic pain. Meta-analysis of six 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.

In 2011, Tan et al published a multi-center randomized double-blind sham-controlled trial of CES for chronic neuropathic pain following spinal cord injury. The study of 105 participants was funded by the Veterans Affairs Rehabilitation Research and Development Service. Sub-perception CES or sham CES was applied for one hour daily at home over 21 days, followed by a six-month open-label phase to assess “as needed” CES usage. The primary outcome measure was daily pre-to post-session changes in pain ratings. The active and sham groups did not differ significantly on average daily pain ratings before (active=5.60, sham=5.41) or after treatment (active=5.00, sham=5.00), but the active CES group had a statistically greater decrease in pain (0.60 vs. 0.41). This is not a clinically significant difference. The only outcome measure that showed a significant group by time interaction after 21 days of treatment was pain interference, although this measure was not comparable between the groups at baseline. Baseline to post-treatment changes in pain intensity, pain quality, pain beliefs and coping strategies, general physical and mental health status, depressive symptomatology, perceived stress, and anxiety did not differ between groups. Eighteen participants (17%) reported that they were using the device by the sixth month of open-label phase.

Parkinson’s 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’s disease.

Smoking Cessation
In 1997, Pickworth et al reported that five days of CES was ineffective for reducing withdrawal symptoms or facilitating smoking cessation in a double-blind randomized controlled trial of 101 cigarette smokers who wish to stop smoking.

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 contradictory. 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 received 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 six
hours, with additional piritramide given on demand. Needles and devices were removed 72
hours postoperatively. A blinded observer found no significant difference between the two
groups in consumption of piritramide during the first 72 hours postoperatively (acupuncture vs.
placebo: 15.3 mg vs. 13.9mg, respectively) or on visual analog scale (VAS scores taken at 0, 2,
24, 48, and 72 hours (average 2.32 vs. 2.62, acupuncture vs. placebo, respectively).

Chronic Low Back Pain
In 2004, Sator-Katzenschlager et al reported a randomized double-blind controlled study of
auricular electro-acupuncture compared to conventional manual auricular acupuncture in 61
patients with chronic low back pain (duration of at least six 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 six 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 weeks’ 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 five in the control group and less than two
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-blind 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 four days per week over six 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<.001). From the beginning of treatment to four 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<.001). Similar changes were observed for BMI (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, Bernateck et al reported the use of the P-Stim device in a
randomized controlled trial 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 six 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 three
months of follow-up. The primary outcome measures were the mean weekly pain intensity and
the disease activity score (DAS-28). At the end of treatment and at three-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 three month follow-up. The clinical significance of a one-point difference in VAS from this small trial is unclear.

**Summary**

CES and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, and anxiety. The literature on CES consists of a number of Randomized controlled trials and systematic review, 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.

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.

**Key Words:**
Cranial electrotherapy stimulation (CES), cranial electrical stimulation, transcranial electrical stimulation, electrical stimulation therapy, Alpha-Stim®, Auricular electrostimulation, Stim™, E-pulse

**Approved by Governing Bodies:**
A number of devices for CES have received marketing clearance through the 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.

The P-Stim™ (NeuroScience Therapy Corp) received marketing clearance through the FDA’s 510(k) process in 2006. The P-Stim™ is intended for use as an electro-acupuncture device to stimulate appropriate auricular acupuncture points.

The E-pulse received 510(k) marketing clearance in 2009, listing the P-Stim™ as a predicate device. The E-pulse is a microprocessor-controlled battery-powered unit designed to administer auricular point nerve stimulation treatment for pain therapy over a 96-hour period.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

**Current Coding:**
The correct code to report the cranial electrical stimulation device is E1399, unlisted DME. Narrative identifying this device should be placed to the right of the CPT code. The manufacturers are encouraging the suppliers to use procedure code E0730 TENS four lead, larger area/multiple nerve stimulation.

Please note that E0730 is not the correct code to report cranial electrical devices.

**HCPCS code:** S8930 
**Current Coding:** Electrical stimulation of auricular acupuncture points; each 15 Minute of personal one-on-one contact with the patient

**References:**
23. www.alpha-stim.com

Policy History:
Medical Policy Manual, April 1982
Re-Evaluated 1989
Medical Policy Group, September 7, 2001
Medical Policy Group, January 2003
Medical Policy Group, February 2004
Medical Policy Group, February 2006 (1)
Medical Policy Group, February 2007 (1)
Medical Policy Group, February 2008 (1)
Medical Policy Group, February 2009 (1)
Medical Policy Group, February 2010 (1): Policy reviewed. No changes
Medical Policy Panel, September 2012
Medial Policy Group, October 2012 (2): Title change, non-coverage policy statement added for Auricular Electrostimulation. Key Points and References updated with literature search through
June 2012. Description, Key Words, and Approved by Governing Bodies updated with auricular electrostimulation information and “also known as” terms for Cranial Electrotherapy Stimulation
Medical Policy Administration Committee, October 2012
Available for comment October 24 through December 10, 2012
Medical Policy Administration Committee, August 2014
Medical Policy Group, August 2014 (5): Policy updated with literature review through July 16, 2014: Updated Description, Key Points and References. No change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.