I. POLICY

Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is investigational as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Electrical stimulation of auricular acupuncture points is investigational as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP-6.020 Transcutaneous Electrical Nerve Stimulation
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO*

*Refer to FEP Medical Policy Manual MP-8.01.58, Cranial Electrotherapy Stimulation (CES) and Auricular Stimulation. The FEP Medical Policy Manual can be found at: www.fepblue.org.
III. DESCRIPTION/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 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 brain networks by direct action in the hypothalamus, limbic system and/or the reticular activating 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 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 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.

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. FDA product code: JXK.

In 2006, the P-Stim™ (NeuroScience Therapy) was cleared for marketing by FDA through the 510(k) process for use as an electroacupuncture device to stimulate appropriate auricular acupuncture points. FDA product code: BWK.

The E-pulse™ was cleared for marketing through the 510(k) process in 2009. FDA determined that this device was substantially equivalent to the P-Stim™. 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. FDA product code: BWK.

IV. RATIONALE

Assessment of efficacy for 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 particularly susceptible to placebo effects. Because of these factors, sham controlled trials are essential to demonstrate the clinical effectiveness of cranial electrotherapy stimulation and auricular electrostimulation compared with alternatives such as continued medical management. Therefore, evidence considered for this review focuses on randomized sham-controlled trials and systematic reviews of RCTs.

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. 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.

Headache

A 2004 Cochrane review of noninvasive treatments for headaches identified 2 poor quality, placebo-controlled, randomized trials of 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.³ Meta-analysis of 6 trials (total N=270 participants) found no significant difference between active and sham stimulation, leading to the conclusion that CES is not as effective for treatment of chronic pain.

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.⁴ 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).⁵ 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.⁶ 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.

Another smaller double-blind, sham-controlled RCT (N=30) found no significant benefit of CES as an add-on in patients with treatment-resistant major depression.⁷ Both active and sham groups showed improvements in depression over the 3 weeks of the study, suggesting a strong placebo effect.

A randomized study on anxiety, included in the 1995 meta-analysis by Klawansky, was the 1976 trial by Passini et al.⁸ 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 rather than the active CES group.
**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.\(^9\)

**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 wanted to stop smoking.\(^{10}\)

### Auricular Electrostimulation

**Acute Pain**
In a 2007 review, Sator-Katzenschlager and Michalek-Sauberer found that studies on P-Stim use in acute pain (eg, oocyte aspiration, molar tooth extraction) were inconsistent.\(^{11}\) A 2011 RCT from Europe tested the efficacy of the P-Stim on 40 female patients undergoing gynecologic surgery.\(^{12}\) 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 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 vs placebo: 15.3 mg vs 13.9 mg, respectively) or in average visual analog scale (VAS) scores taken at 0, 2, 24, 48, and 72 hours (acupuncture vs placebo, average 2.32 vs 2.62, respectively).

**Chronic Low Back Pain**
At the time this evidence review was created (2011), use of the P-Stim had been reported only in European trials. In 2004, Sator-Katzenschlager et al reported a double-blind RCT of auricular electro-acupuncture compared with conventional manual auricular acupuncture in 61 patients with chronic low back pain (at least 6 months).\(^{13}\) 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 electro-acupuncture 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 electro-acupuncture. This study was limited by the small number of participants. In 2003, this group of investigators had reported similar effects in a smaller randomized study of 21 patients with chronic cervical pain.\(^{14}\)
Obesity
The same group of investigators also reported 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.

Rheumatoid Arthritis
In a European study from 2008, Bernateck et al 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 (eg, 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.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in January 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Summary of Evidence
The evidence for cranial electrotherapy stimulation in individuals who have acute or chronic pain or various psychiatric, behavioral, or neurologic conditions (eg, addiction, obesity, Parkinson disease, depression, anxiety, schizophrenia, personality disorder) includes a number of randomized, double-blind, 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. 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.

The evidence for auricular electrostimulation in individuals who have acute or chronic pain (eg, acute pain from surgical procedures, chronic pain from osteoarthritis, rheumatoid arthritis, spinal cord injury, chronic back, neck pain) or obesity 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 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 electrostimulation 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.

V. DEFINITIONS

NA

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and
providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

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IX. REFERENCES

### Policy Title
CRANIAL ELECTROTHERAPY STIMULATION (CES) AND AURICULAR ELECTROSTIMULATION

<table>
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Other sources

X. POLICY HISTORY

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