CRANIAL ELECTROTHERAPY STIMULATION

Policy Number: BH727CESBCP_042018  Effective Date: April 11, 2018

Table of Contents

- BENEFIT CONSIDERATIONS .................................................. 1
- COVERAGE RATIONALE .......................................................... 1
- DESCRIPTION OF SERVICES .................................................. 1
- CLINICAL EVIDENCE ............................................................. 2
- U.S. FOOD AND DRUG ADMINISTRATION ............................. 3
- CENTERS FOR MEDICARE AND MEDICAID SERVICES ......... 3
- APPLICABLE CODES ............................................................. 4
- REFERENCES ......................................................................... 4
- HISTORY/REVISION INFORMATION ........................................ 4

BENEFIT CONSIDERATIONS

Before using this policy, please check the member-specific benefit plan document and any federal or state mandates, if applicable.

COVERAGE RATIONALE

Cranial electrotherapy stimulation (CES) is unproven and not medically necessary for the treatment of behavioral disorders including, but not limited to, depression and anxiety.

A review of the clinical literature does not support cranial electrotherapy stimulation as a significant intervention in treating behavioral disorders, such as depression and anxiety. A number of substantial limitations exist in the reviewed studies, such as wide variation of treatment protocols, small sample sizes, and inadequacies in study design.

The requested service or procedure must be reviewed against the language in the member's benefit document. When the requested service or procedure is limited or excluded from the member's benefit document, or is otherwise defined differently, it is the terms of the member's benefit document that prevails.

Per the specific requirements of the plan, health care services or supplies may not be covered when inconsistent with Level of Care Guidelines and/or evidence-based clinical guidelines.

All services must be provided by or under the direction of a properly qualified behavioral health provider.

DESCRIPTION OF SERVICES

Cranial electrotherapy stimulation (CES), a form of complementary and alternative medicine (CAM), is a device that applies micrcurrents to a patient’s head to treat insomnia and some behavioral disorders, such as depression and anxiety.

Marketed CES devices have two basic components. The first is an enclosure that houses the electronics and is responsible for generating the electrical stimulation delivered to the patient. This usually also contains the controls with which the patient or physician can modify the stimulation. The second primary component is a set of cutaneous electrodes, which are placed on the head. These may be produced either by a third party or by the CES manufacturer (FDA, 2011).
CES current is delivered at approximately nine volts. Treatment typically involves 20-60 min of daily stimulation for three weeks, based on a current strength that is comfortable to the patient. This is often followed by less frequent treatments that may go on indefinitely (Mischoulon, et al 2015).

CES devices are not to be confused with transcutaneous electrical nerve stimulation (TENS) devices. TENS devices are primarily used for pain relief, and typically have a higher output than CES devices.

CES may be identified by other terms in the research literature, including “transcranial electrotherapy (TCET)”, “transcranial electrostimulation”, “cerebral electrostimulation”, “neuroelectric therapy (NET)”, “neurotransmitter modulation”, “electrosleep”, etc.

**CLINICAL EVIDENCE**

**Summary of Clinical Evidence**
A review of the current literature does not support cranial electrotherapy stimulation (CES) as a significant intervention in treating depression and anxiety disorders.

A number of substantial limitations were identified in the published literature regarding CES for treatment of behavioral disorders. Interpreting the various findings in the CES literature is difficult due to a wide variety of marketed CES devices, different treatment protocols, and a lack of detailed stimulation parameters in many published trials (Mischoulon, et al 2015). The reviewed studies also had key limitations in study design and methodology, such as small sample sizes, and a heightened potential for the placebo effect. There is also a shortage of published literature that compares CES to established, proven therapies for both depression and anxiety. Many of the authors have noted that further research on CES for behavioral disorders is necessary. Particularly, well-designed studies with larger sample sizes are needed.

CES devices appear to be relatively safe for the treatment of behavioral disorders when used as prescribed.

**Clinical Trials**
Mischoulon and colleagues (2015) examined the efficacy and safety of a cranial electrical stimulator (CES) device at a fixed setting in subjects with treatment-resistant major depressive disorder (MDD). A total of 30 subjects (mean age = 48) were enrolled in the study. Severity of depression was determined by Structured Interview for the HAM-D-17; scores 15-23 were required for inclusion. Subjects were required to be taking current antidepressant and not responding in a satisfactory manner. A total of 17 subjects were randomized to CES treatment, and 13 randomized to sham (inactive CES) treatment. Subjects received their first treatment (or sham) at a clinic site for 20 min, and were then allowed to take the device home and self-administer CES for remaining treatments (total of 5 per week, no more than once daily), until their next appointment - during the 3-week double blind treatment course, all subjects received one clinician-supervised weekly stimulation during their regular clinic visit. Following completion of the 3-week double-blind phase, subjects were given an active CES device to use at home for 3 more weeks, with weekly check-in visits at the clinic. A total of 15 of the 17 subjects (88%) in the active treatment group completed all treatment sessions; all 13 subjects randomized to sham completed all treatment sessions. Both treatment groups demonstrated improvement of 3-5 points in HAM-D-17 scores, with no significant differences observed between groups. Remission rates were 12% for CES and 15% for sham, a non-significant difference. CES was deemed safe, with good tolerability. The authors acknowledged study limitations of a small sample and lack of active comparator therapy. The authors conclude that although both treatment groups improved significantly, CES treatment at the setting chosen did not separate from sham in the sample. The authors could not rule out that the benefit from the setting used in this particular form of CES was due to placebo effects.

McClure and colleagues (2015) conducted a pilot study to investigate the effectiveness of cranial electrotherapy stimulation (CES) for the treatment of bipolar II depression (BD II). The 12-week study design included the following three stages: double-blind phase (weeks 1–2), open-label phase (weeks 3–4), and follow-up phase (weeks 5–12). Each participant visited the study site five times per week for treatment. A total of 16 participants, with a mean age of 47, were included in the study. Participants were randomized to either active CES or sham treatment using a method of random sequence generator. At the end of phase I, patients whose scores on the HAM-D were ≤ 7 were considered to be in remission and were moved into the follow-up phase of the trial. All other participants, who had HAM-D scores > 7, were crossed over to the open-label treatment phase for another 2 weeks. Patients were excluded from the study if they had a history of treatment resistant bipolar II depression, were in a manic or mixed episode, had a diagnosis of unipolar depression, schizophrenia, schizoaffective disorder, substance dependence or abuse within the past year, an active suicidal plan, or history of suicide attempt within the past 12 months. Participants were instructed to maintain stable dosages of their antidepressant medications for 2 weeks before entering the study and throughout the treatment period. Participants were assessed at baseline and then weekly throughout the study with the BDI, the HAM-D-17, and the YMRS. The active group participants (n = 7) received 2 mA CES treatment for 20 minutes whereas the sham group (n = 9) had the CES device turned on and off. Active CES treatment, but not sham treatment, was
associated with a significant decrease in the Beck Depression Inventory (BDI) scores from baseline to the second week, and maintained significance until week 4. Clinician-rated HAM-D scores showed significant improvement for both groups. There was no difference between groups in side effects frequency. The authors note that data was collected from a small sample size and a specific sub-population of bipolar II depressed individuals, limiting the generalizability of the findings. The authors conclude that results of this small study indicate that CES may be a safe and effective treatment for BD II, and suggest that further studies on safety and efficacy of CES may be warranted.

Barclay and Barclay (2014) used a randomized, double-blind, sham controlled design to examine the effectiveness of cranial electrotherapy stimulation (CES) as a treatment for anxiety disorders and comorbid depression in a primary care setting. All participants were required to score on the lower end of mild on the HAM-A, > 15. Scores on the HAM-D-17 were allowed to range through the very severe range provided the HAM-A was the dominant score. Participants taking antidepressants were allowed to participate as long as the medication and dose were stable for at least 3 months prior to entering the study and the individual was still exhibiting symptoms of anxiety. Baseline and follow-up measurements (weeks 1, 3, and 5) included the HAM-A and HAM-D-17. During the study, each participant was required to treat themselves daily for one hour. Participants were provided treatment logs to document the day, time, and duration of treatment. A total of 115 participants agreed to participate and were randomized into two groups: an active CES group (n = 60) and a sham CES group (n = 55). There were no significant differences between groups prior to treatment. Analyses found a significant difference between the active CES group and the sham CES group on anxiety and depression scores from baseline to endpoint of study in favor of the active CES group. In the active CES group, 83% had a decrease of > 50% in anxiety scores from baseline to endpoint and 82% had a decrease of > 50% in depression scores from baseline to endpoint. The authors note that a limitation of this study was the small number of participants (n = 23) who had an anxiety disorder and comorbid depression, and that additional research is needed that includes a much larger number of participants with an anxiety disorder and comorbid depression. No adverse effects from CES were reported during the study.

**Systematic Reviews/Meta-Analyses**

Kavirajan and colleagues (2014) conducted a Cochrane systematic review to assess the effectiveness and safety of alternating current cranial electrotherapy stimulation (CES) compared with sham CES for acute depression. The authors searched the Cochrane Collaboration Depression, Anxiety and Neurosis review group’s specialized register, which contains relevant randomized controlled trials (RCTs). This search examined a total of 270 RCTs. Selection criteria included RCTs of CES versus sham CES for the acute treatment of depressive disorder in adults aged 18-75 years. Only 7 studies were judged rigorous enough for full eligibility assessment, but were ultimately excluded for various reasons (failure to use specific diagnostic criteria; focus on subjects with chronic rather than acute depression; lack of appropriate comparator groups; and sham CES that did not produce tingling, potentially compromising the blind). The authors reported that no studies met the inclusion criteria for this review. The authors concluded that there are insufficient methodologically rigorous studies of CES in treatment of acute depression, and that there is a need for double-blind RCTs of CES in the treatment of acute depression.

**Professional Societies**

**American Psychiatric Association (APA):** Cranial electrotherapy stimulation is not listed as a form of complementary and alternative medication in the APA’s practice guidelines for major depression (APA, 2010).

**U.S. FOOD AND DRUG ADMINISTRATION**

The FDA regulates CES devices through its 510(k) process, and has granted marketing clearance to several CES products. The first CES devices were granted clearance in 1977, and relied on a comparison to perduricate devices in order to demonstrate substantial equivalence.

In 2011, the FDA published a proposed rule to require premarket approval for CES devices. Based on the review of submissions received from CES manufacturers and literature review, the FDA’s Neurological Devices Panel concluded “that the effectiveness of CES has not been established by adequate scientific evidence.” However, any applicant whose device was legally in commercial distribution before May 1976, or whose device has been found to be substantially equivalent to such a device, was permitted to continue marketing such Class III devices (FDA, 2011).

In June 2014, the FDA withdrew the proposed 2011 rule. After consideration of comments in response to the proposed rule and other deliberations, the FDA determined that there was sufficient information to establish special controls, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for CES devices. The current indication language is that the device is used for treatment of insomnia, depression, and anxiety (DHHS, 2014).

In the United States, CES devices are cleared for prescription use only.
Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) for cranial electrotherapy stimulation could not be identified.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member-specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (unattended)</td>
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<tr>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (manual) each 15 minutes</td>
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<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<td>G0283</td>
<td>Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
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REFERENCES


HISTORY/REVISION INFORMATION

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