



Cranial Electrotherapy Stimulation

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Introduction & Instructions for Use

Introduction

Behavioral Clinical Policies are a set of objective and evidence-based behavioral health criteria used by medical necessity plans to standardize coverage determinations, promote evidence-based practices, and support members’ recovery, resiliency, and wellbeing for behavioral health benefit plans that are managed by Optum®.

Instructions for Use

This guideline is used to make coverage determinations as well as to inform discussions about evidence-based practices and discharge planning for behavioral health benefit plans managed by Optum. When deciding coverage, the member’s specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member’s benefits prior to using this guideline. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this guideline and the member’s specific benefit, the member’s specific benefit supersedes this guideline. Other clinical criteria may

apply. Optum reserves the right, in its sole discretion, to modify its clinical criteria as necessary using the process described in Clinical Criteria.

This guideline is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Optum may develop clinical criteria or adopt externally-developed clinical criteria that supersede this guideline when required to do so by contract or regulation.

Benefit Considerations

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

Description of Service

Cranial electrical stimulation (CES) is a non-invasive practice using low-intensity electrical current applied to the head. CES is related, yet different, than other forms of transcranial electrical stimulation including electroconvulsive therapy, transcranial direct current stimulation (tDCS), and high-definition transcranial direct current stimulation (Shekelle, 2018).

Examples of CES devices that are FDA-cleared for marketing are the Alpha-Stim® products, Fisher-Wallace Cranial Electrical Stimulator®, CES-Ultra™, and Cervella™. The devices are FDA-cleared for the treatment of anxiety, depression, and insomnia. The placement of electrodes and the amount and type of current differ among these devices (Department of Health & Human Services [DHHS] & FDA, 2019; Shekelle, 2018).

CES may be identified by other terms in the research literature, including “transcranial electrotherapy (TCET)”, “transcranial electrostimulation”, “cranial electrostimulation”, “neuroelectric therapy (NET)”, “neurotransmitter modulation”, “electrosleep”, etc. (Shekelle, 2018).

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. Several substantial limitations exist in the reviewed studies, such as wide variation of treatment protocols, small sample sizes, and inadequacies in study design (McClure et al., 2015; Shekelle, 2018).

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 evidence-based clinical guidelines.

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

Summary of Clinical Evidence

A review of the current literature does not support cranial electrotherapy stimulation (CES) as a viable intervention in treating behavioral disorders including, but not limited to, depression and anxiety.

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 (Shekelle, 2018).

Current research shows that CES devices appear to be relatively safe due to no reports of serious side effects (Shekelle, 2018).

Systematic Reviews and Meta-Analyses

Ching and associates (2022) completed a systemic review and meta-analysis to investigate the efficacy and tolerability of cranial electrotherapy stimulation (CES) for individuals with anxiety symptoms. RCTs investigating the effects of CES as monotherapy or combination with other treatment were eligible, 11 RCTs were included in the review (n = 794, mean age: 41.4, mean population of female: 64.8%). The primary (anxiety symptoms) and secondary outcomes (depression symptoms) were determined as mean change in scores for anxiety or depression symptoms, utilizing a validated scale for these symptoms. Results showed that CES significantly decreased the anxiety symptoms compared to sham (Hedge's $g = -0.625$, 95% confidence intervals (CIs) $= -0.952$ to -0.298 , $P < 0.001$) with moderate effect size. Results for the secondary outcome, CES significantly decreased depressive symptoms in individuals with anxiety disorders when compared to sham (Hedges' $g = -0.648$, 95% CIs $= -1.062$ to -0.234 , $P = 0.002$). Limitations for the included studies were noted such as different CES protocols, inadequate follow-up data to identify long-term durability, and the mechanism of action for CES remains unclear. Future studies are needed to establish the most effective stimulation parameters, to establish durability data, and to examine the principal mechanism of CES in reducing psychiatric symptoms.

Price et al. (2021) completed a meta-analyses of cranial electrotherapy stimulation in the treatment of depression. The meta-analyses comprised 5 randomized controlled trials (RCTs) with a combined 242 participants. The participants were both male and female, ages 8-65. The efficacy of the Alpha-Stim CES device was the subject of the RCTs. The assessment tools utilized for pretest and posttest were the Hospital Anxiety and Depression Scale (HADS), the Hamilton Depression Rating Scale-17 (HAM-D17), the Brief Symptom Inventory (BSI), and the Zung Depression Scale. The authors report that all 5 RCTs found a significant decrease of depression and anxiety symptoms with the use of CES. The results showed the average effect for the RCTs was calculated as $d = -0.69$ (i.e., the mean depression level at posttest for the active group was -0.69 standard deviations lower than the mean depression level for the sham group), a medium effect. Limitations noted were that many participants were self-selected which can lead to selection bias, in addition to the limited number of participants in each study.

Shekelle and associates (2018) prepared a systematic review for the Department of Veterans Affairs (VA) regarding the effectiveness and risks of cranial electrical stimulation for the treatment of pain, depression, anxiety, PTSD, and insomnia. Randomized controlled trials that met eligibility criteria were a total of 26. There were 14 RCTs of individuals with chronic pain, 3 RCTs of individuals with depression, 5 RCTs of individuals with depression and anxiety, 2 RCTs of individuals with insomnia, 1 RCT of individuals with anxiety and insomnia and 1 RCT with anxiety alone. There were no RCTs with post-traumatic stress disorder (PTSD) as a diagnosis. An array of cranial electrical stimulation devices and techniques were used. The results of this systematic review include that the evidence is insufficient to support that CES has clinically valuable effects on headache, fibromyalgia, neuromuscular pain, depression, PTSD, or insomnia. There is low-strength evidence for a possible beneficial effect of modest size in patients who have anxiety with depression. CES is most likely safe, due to no reports of serious side effects, although reporting bias exists. The authors conclude that future research should focus on adequately blinded studies of ample size in order to identify clinical benefits. In addition, the authors note that useful data regarding if treatment benefits continue after treatment is discontinued, or if relapse occurs, and when relapse occurs. Lastly, long-term safety studies are needed.

Kavirajan and colleagues (2014) conducted a Cochrane systematic review to assess the efficacy 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 18-75 years old. Initially, 7 studies were judged rigorous enough for full eligibility assessment, but were eventually 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.

Clinical Trials & Studies

Kim et al. (2021) conducted a randomized double-blind placebo-controlled trial to examine the effects of a home-based CES that uses in-ear electrodes similar to headphones, on anxiety-related symptoms and resting-state brain activity. Participants were nonclinical volunteer adults, between the ages 19 and 65 years. Participants (n=66) had a self-reported score above 4 on both anxiety and perceived stress 0-10 visual analogue scales (VAS), which were separately administered. Participants were randomly assigned to the active (n = 33) or sham stimulation groups (n = 33). Baseline assessments and effectiveness was measured utilizing State-Trait Anxiety Inventory (STAI)/State Anxiety Inventory (SAI), Beck Depression Inventory (BDI), Wisconsin Card Sort Test (WCST), and resting-state brain activity via electroencephalography (EEG). Participants each received the first CES treatment immediately following the baseline assessment. The remaining 20 treatments were completed independently at home, daily for 3 weeks. Results for the effect of CES on symptoms change yielded a significant effect with the State Anxiety Inventory (SAI) ($p = .039$), with the SAI score significantly reduced post-intervention compared to the baseline in the active group only ($p = .015$). In the WCST-Categories Completed, there was a trend toward positive effects ($p = .061$), in which the post-intervention active group scored higher than the sham ($p = .010$), and the score was increased post-intervention compared to baseline in the active group only ($p = .009$). Results for the effects of EEG activity and symptoms change revealed that SAI was not statistically significant with the following scalp electrode locations: FC3 ($p = .028$) and F7 ($p = .038$) electrodes in the theta frequency band. The BDI indicated significance with the scalp electrode locations: CP2 ($p = .002$), P6 ($p = .016$) and CP6 ($p = .020$). Limitations include lack of generalizability due to small sample size and nonclinical population, the brief treatment period of 3 weeks, utilizing a single cognitive function test, and lack of durability data. Further high-quality RCTs with larger sample sizes are required to validate the treatment efficacy and durability of CES for behavioral disorders.

Wu and colleagues (2020) completed a double-blind, randomized, sham-controlled study of cranial electrotherapy stimulation as an add-on treatment for tic disorders (TD) in children and adolescents. The study was conducted at Xijing Hospital in China from May 1, 2017 to September 31, 2018. A total of 62 participants aged 6–17 years with TD plus a lack of clinical response to 4 weeks of pharmacotherapy were enrolled. Participants were divided randomly into 2 groups and administered 4 weeks of treatment, including 30-minute sessions of active CES (500 μ A–2 mA) or sham CES (lower than 100 μ A) per day for 40 days on weekdays. During the study, participants were instructed to continue their medication regimen. Assessments used to monitor symptoms were the Yale Global Tic Severity Scale (YGTSS), Clinical Global Impression-severity of illness severity (CGI-S), and the Hamilton Anxiety Scale-14 items (HAMA-14); these assessments were performed at baseline, week 2, and week 4. There was no significant difference in age, gender, baseline scores of YGTSS, HAMA-14 and CGI scores between the two groups. Fifty-three patients (34 males and 9 females) completed the trial, including 29 in the active CES group and 24 in the sham CES group. Both groups showed clinical improvement in tic severities compared to baseline respectively at week 4. The authors reported both active and sham groups had similar side effects, indicating that CES was tolerable and safe. The most recurrent complaint was skin discomfort of the ears. A limitation denoted is that participants were taking psychotropic drugs known to influence brain excitability. Results revealed that participants receiving active CES showed a reduction of 31.66 % in YGTSS score, compared with 23.96 % in participants in sham CES group, resulting in no significant difference between the two groups ($t = 1.54$, $p = 0.13$). The authors conclude that the improvement for tic severity may be related to placebo effect. Lastly, the authors acknowledge larger participant samples are needed to assess whether 4-week CES is clinically effective in reducing twitch severity.

Yennurajalingam and associates (2018) conducted a preliminary study of 33 individuals diagnosed with advanced cancer, plus one or more of depression, anxiety, insomnia, and pain. The method used was a one group open label pre- and post-intervention study, with 4-weeks of CES treatments. The CES device used was the Alpha-Stim[®] applied 60 minutes daily for 4 weeks. The Hospital Anxiety and Depression Scale (HADS) 14-item scale was used to measure anxiety and depression. The

HADS results showed that CES was associated with substantial improvements in depression ($P=0.024$) and anxiety ($P<0.001$). The authors conclude that the findings support further research on this topic.

Mischoulon and colleagues (2015) examined the efficacy and safety of a 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 examine 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, participants 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. Individuals were excluded from the study if they had a history of treatment resistant bipolar II depression, were in a current manic or mixed episode, and had a history of diagnosis with 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 unchanging 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 CES treatments for 20 minutes whereas the sham group ($n = 9$) had the CES device turned on and off. Active CES treatment, rather than 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. The HAM-D scores showed significant improvement for both groups. The authors note the small sample size, within a specific sub-population of bipolar II depressed individuals, limits ability to generalize 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 are needed.

Guidelines & Consensus Statements

- *American Psychiatric Association (APA)*
 - Cranial electrotherapy stimulation is not listed as an effective treatment in the APA's practice guidelines for major depression (2010), posttraumatic stress disorder (2004), or bipolar disorder (2002).
- *American Academy of Child and Adolescent Psychiatry (AACAP)*
 - Cranial electrotherapy stimulation is not recommended as a treatment option in practice parameters for children and adolescents with depressive disorders (2007), anxiety disorders (2020), bipolar disorder (2007), or posttraumatic stress disorder (2010).
- *The Canadian Network for Mood and Anxiety Treatments (CANMAT)* and International Society for Bipolar Disorders (ISBD)
 - The 2018 guidelines for the management of patients with bipolar disorder reports there is insufficient data to support cranial electrotherapy stimulation as a treatment for bipolar depression. In addition, the Canadian Network for Mood

and Anxiety Treatments (CANMAT) 2016 clinical guidelines for the management of adults with major depressive disorder does not endorse cranial electrotherapy stimulation as a treatment for depression.

- *The Department of Veterans Affairs (VA)*
 - Cranial electrotherapy stimulation is not suggested as an effective treatment in the VA/DOD practice guideline for the management of major depressive disorder (VA/DOD, 2022) nor the practice guideline for the management of posttraumatic stress disorder (VA/DOD, 2017).
- *The Royal Australian and New Zealand College of Psychiatrists (RANZCP)*
 - The clinical practice guidelines for mood disorders (2020) and the RANZCP practice guidelines for the treatment of panic disorder, social anxiety disorder, and generalized anxiety disorder (2018) and does not list or recommend cranial electrotherapy stimulation as an effective treatment option.

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. In 2014, the FDA determined that there was sufficient information to establish special controls, and that these special controls, combined with general controls, will provide a reasonable assurance of safety and effectiveness for CES devices. The indication language states that the device is used for treatment of insomnia, depression, and anxiety (Department of Health & Human Services [DHHS] & FDA, 2014). In 2018, the FDA published Class III premarket approval for cranial electrotherapy stimulator devices to treat insomnia, depression, or anxiety. In the United States, CES devices are prescription use only. Effective December 20, 2019, the FDA issued a final order to reclassify the cranial electrotherapy stimulator device intended to treat anxiety and/or insomnia, from a class III device, into class II (special controls) and subject to premarket notification. Class III premarket approval continues when intended to treat depression (DHHS & FDA, 2019).

Centers for Medicare and Medicaid Services

There are no Medicare National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs) addressing cranial electrotherapy stimulation.

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 clinical criteria may apply.

Procedure Codes	Description
K1002	Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type

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Revision History

Date	Summary of Changes
04/11/2017	Version 1
04/11/2018	Annual Update: Updated formatting, checked references. Approved by UMC.
10/21/2019	Annual Update
10/19/2020	Annual update
10/19/2021	Annual Update
06/21/2022	Update to procedure code grid
10/18/2022	Annual Review: updated references/sources.