



United Behavioral Health

Behavioral Clinical Policy: Cranial Electrotherapy Stimulation

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Table of Contents

[Introduction](#)

[Instructions for Use](#)

[Benefit Considerations](#)

[Description of Service](#)

[Coverage Rationale](#)

[Clinical Evidence](#)

[Applicable Codes](#)

[References](#)

[Revision History](#)

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®¹.

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.

¹ Optum is a brand used by United Behavioral Health and its affiliates.

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. (Department of Veterans Affairs (VA), 2018).

The CES devices that are FDA-cleared for marketing are the Alpha-Stim[®] products and the Fisher-Wallace Cranial Electrical Stimulator[®]; they are used for the treatment of anxiety, depression, and insomnia. The placement of electrodes and the amount and type of current differ among these devices (VA, 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. (VA, 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. 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 (McClure et al., 2015; VA, 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 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.

CLINICAL EVIDENCE

Summary of Clinical Evidence

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

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 (VA, 2018).

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

Clinical Trials & Studies

Yennurajalingam and colleagues (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.

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.

Systematic Reviews & Meta-Analyses

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.

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 (APA, 2010), or the practice guidelines for bipolar disorder (APA, 2002).

American Academy of Child and Adolescent Psychiatry: Cranial electrotherapy stimulation is not recommended as a treatment option in practice parameters for children and adolescents with depressive disorders and the practice parameters for children and adolescents with bipolar disorder (AACAP, 2007).

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, 2016).

The National Institute for Health and Care Excellence (NICE): Cranial electrotherapy stimulation is not listed as recommendation according to the published clinical guideline on depression in adults: recognition and management (NICE, 2018).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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 current indication language is that the device is used for treatment of insomnia, depression, and anxiety (Department of Health & Human Services, 2014). In addition, 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 (FDA, 2018).

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
E1399	Durable medical equipment, miscellaneous

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REVISION HISTORY

Date	Action/Description
04/11/2017	<ul style="list-style-type: none">Version 1
04/11/2018	<ul style="list-style-type: none">Annual Update: Updated formatting, checked references. Approved by UMC.
10/21/2019	<ul style="list-style-type: none">Annual Update