

MEDICAL POLICY		Cranial Electrical Stimulation	
Effective Date: 1/1/2021		Section: BH	Policy No: 001
 1/1/2021		Medical Policy Committee Approved Date: 9/2020	
Medical Officer	Date		

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

## SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

## APPLIES TO:

All lines of business

## BENEFIT APPLICATION

### Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

### POLICY CRITERIA

Cranial electrical stimulation is considered **not medically necessary and not covered** for the treatment of any indication, including but not limited to depression or anxiety disorders.

Link to [Policy Summary](#)

## CPT/HCPCS CODES

### All Lines of Business

#### Unlisted Codes

All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be **denied as not covered**.

E1399	Durable medical equipment, miscellaneous
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## DESCRIPTION

### Depression

Depression is a mood disorder that causes a persistent feeling of sadness and loss of interest. Prevalence is approximately 1% to 3% worldwide, representing the fourth leading cause of disease burden globally. Currents treatments include psychological therapy and antidepressant medications.

### Anxiety Disorders

Anxiety disorders refer to a group of mental disorders characterized by excessive worry and anxiety causing significant distress and impairment. Examples of anxiety disorders include generalized anxiety disorder,

### Cranial Electrical Stimulation

Cranial electrical stimulation works by sending low-level electrical currents to the head via electrodes. The exact mechanism of action remains unclear but has been hypothesized to affect particular areas of the brain that play important roles in the body's hormones and emotions. The treatment has been proposed for the treatment of a variety of chronic conditions including, but not limited to stress, alcoholism, drug addiction, anxiety and depression.

## REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of cranial electrical stimulation as a treatment for depression or anxiety. Below is a summary of the available evidence identified through July 2020.

### *Systematic Reviews*

- In 2018, the Department of Veterans Affairs conducted a systematic review assessing the safety and efficacy of cranial electrical stimulation (CES) for the treatment of pain, depression, anxiety, PTSD and insomnia.<sup>1</sup> Independent investigators systematically searched the literature through September 2017, identified eligible studies, assessed study quality, and extracted data. In total, 28 publications from 26 RCTs were included for review. Four old RCTs (over 40 years) and one recent RCT provided low strength evidence of a possible benefit of CES compared to sham in patients with anxiety and depression at 5-week follow-up, although none of these studies assessed more than 30 patients. RCT results were conflicting for fibromyalgia, headache, other painful conditions, depression and insomnia. There is low strength evidence that CES does not cause serious side effects. All RCTs were judged to be at high risk of bias. Limitations included the lack of RCTs assessing the same patient population, lack of blinding, small sample sizes and inadequate follow-up.
- In 2017, Cochrane conducted a systematic review assessing the safety and efficacy of alternating current cranial electrotherapy stimulation (CES) compared with sham CES for the treatment of acute depression.<sup>2</sup> Independent investigators systematically searched the literature through

February 2014, identified eligible studies, assessed study quality, and extracted data. No studies met the inclusion criteria for review. Investigators concluded that evidence is insufficient to support the use of CES and that double-blind RCTs are necessary to determine efficacy.

## CLINICAL PRACTICE GUIDELINES

No relevant clinical practice guidelines addressing cranial electrical stimulation were identified.

## CENTERS FOR MEDICARE & MEDICAID

As of 7/20/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses cranial electrical stimulation for the treatment of any indication.

## POLICY SUMMARY

Evidence is insufficient to support the use of cranial electrical stimulation for the treatment of any indication, including but not limited to depression and anxiety disorders. There is a lack of high-quality studies conducted within the past 10-years that are randomized, blinded, and assess large populations with long-term follow-up. Low-quality evidence from studies conducted decades ago suggests that CES may be helpful in the treatment of some anxiety disorders but new trials are needed to validate these findings.

## INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

## REGULATORY STATUS

### U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) has granted 510(k) approval for multiple cranial electrotherapy stimulators including, but not limited to the following:

- Alpha-Stim® Cs (Electromedical Products, Inc)
- BR-2 Biorest (Biorest, Inc)
- Biotron18 (Biotronics Corp)

- CES Ultra™ (Neuro-Fitness, LLC)
- Elexoma Medic (Redplane AG)
- FM 10/C (Johari Digital Healthcare, Ltd)
- HP-1 Healthpax or Nurtipax (Health Directions, Inc)
- LB-2000 (Life Balance Intl., Inc)
- LISS SBI202-B and SBI201-M (Medical Consultants Intl., Ltd)
- NET-2000 Microcurrent Stimulator (Auri-Stim Medical, Inc)
- NF-1 Mindpeace (NeuroFitness)
- NH 2002 (Life Balance Intl., Inc.)
- NTI-1000 (Neurotek, Inc)
- TESA-1 (Kalaco Scientific, Inc.)

#### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

## **REFERENCES**

1. Shekelle PG, Cook IA, West Los Angeles V. *The effectiveness and risks of cranial electrical stimulation for the treatment of pain, depression, anxiety, PTSD, and insomnia: A systematic review*. Department of Veterans Affairs; 2018.
2. Roh H-T, So W-Y. Cranial electrotherapy stimulation affects mood state but not levels of peripheral neurotrophic factors or hypothalamic-pituitary-adrenal axis regulation. *Technology and Health Care*. 2017;25(3):403-412