MEDICAL POLICY	Cranial Electrical Stimulation
Effective Date: 10/1/2021  10/1/2021 Medical Officer Date	Medical Policy Number: 257 Medical Policy Committee Approved Date: 9/2020; 9/2021

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

I. 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

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 activate 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 2021.

Systematic Reviews

- In 2017 (updated 2021), Hayes conducted a systematic review assessing the safety and efficacy of transcranial direct current stimulation (tDCS) for depression.[1] In total, 11 RCTs were included for review. Sample sizes ranged from 22 to 245 patients. Outcomes of interest included assessments of depression, anxiety, cognitive and neuropsychological function, and complications. Follow-up varied from none to 1 month. The 11 reviewed studies of tDCS for treatment of depression were determined to not provide consistent evidence of benefit. Larger studies usually reported that tDCS relieved depression symptoms more effectively than sham tDCS treatment; however, the magnitude of the effect is unclear since not all patients achieved complete remission from depression, and the durability of any benefits are unknown due to the lack of long-term follow-up in these studies. Investigators concluded that a large body of low-quality evidence has found that tDCS for treatment of depression is reasonably safe, but there is inconsistent evidence that this treatment is beneficial. Additional large, well-designed studies were judged necessary to determine the optimal treatment parameters for tDCS and to evaluate the long-term safety and effectiveness of tDCS relative to antidepressant medications and CCT

for treatment of depression. Hayes ultimately assigned a "C" rating (potential but unproven benefit).

- 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.[2] 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.[3] 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

International Federation of Clinical Neurophysiologists (IFCN)

In 2017, the IFCN published evidence-based guidelines addressing the therapeutic use of transcranial direct current stimulation.[4] Authors stated that tDCS has probable but not definite efficacy for treatment of nondrug-resistant major depression when administered with the anode over the left dorsolateral prefrontal complex (DLPFC) and cathode over the right orbitofrontal area. However, authors also concluded that tDCS is probably ineffective for drug-resistant major depression and there is insufficient evidence to develop a recommendation for treatment of depression with tDCS using an anode over the left DLPFC and a cathode over the right DLPFC .

National Institute for Health and Care Excellence (NICE)

In 2015, the NICE published guidelines addressing transcranial direct current stimulation (tDCS) for depression.[5] On the basis of published evidence, NICE concluded that treatment of depression with tDCS did not raise any major safety concerns but there is uncertainty about mode of administration, number of treatment sessions needed, and duration of treatment effects. Therefore, the NICE recommended that this procedure only be used after establishment of special arrangements for clinical governance, patient consent and audit or research.

CENTERS FOR MEDICARE & MEDICAID

As of 8/12/2021, 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. Moreover, there are no evidence-based clinical practice guidelines that support the use of cranial electrical stimulation for the treatment of any indication.

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 SBl202-B and SBl201-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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Hayes Inc. Transcranial Direct Current Stimulation for Depression. https://evidence.hayesinc.com/report/dir.transcranial2926. Published 2021. Accessed 8/12/2021.
2. 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.
3. 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
4. Lefaucheur J-P, Antal A, Ayache SS, et al. Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS). *Clinical Neurophysiology.* 2017;128(1):56-92
5. National Institute for Health and Care Excellence. Transcranial direct current stimulation (tDCS) for depression. https://www.nice.org.uk/guidance/ipg530. Published 2015. Accessed 8/12/2021.