IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Cranial electrostimulation therapy (CES), also called cranial electrotherapy stimulation, involves passing small electrical impulses across the head, usually from electrodes placed on or near both ears. Although the mechanism of action is not clearly understood, it is hypothesized that electrical currents emitted from CES may positively impact the limbic system, the reticular activating system and/or the hypothalamus, resetting the brain to improved homeostasis levels. [1]

CES is proposed for use in treating a variety of chronic conditions including, but not limited to treatment of stress, alcoholism and drug addiction, headache, cognitive dysfunction in head injured patients, psychiatric conditions, reflex sympathetic dystrophy and multiple sclerosis. Because many of these indications require long-term therapy with medications which may be costly, CES has been proposed as a cost-effective, non-invasive alternative to standard treatment.

Regulatory Status

The U.S. Food and Drug Administration (FDA) has granted 510(k) approval for a number of cranial electrotherapy stimulators including 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.)

Marketing clearance via the 510(k) process does not require data regarding clinical efficacy.

Notes:

Some cranial electrostimulation therapy (CES) devices may also be FDA approved to apply electrical stimulation to peripheral nerves [e.g., transcutaneous electrical nerve stimulation (TENS)]. This policy addresses cranial electrical stimulation that targets the brain only; electrical stimulation of peripheral nerves for the treatment of pain or other indications is addressed in separate policies (see Medical Policy, see Cross References, DME-83 for an index of other electrical stimulation policies).

MEDICAL POLICY CRITERIA

Cranial electrostimulation therapy is considered investigational for all indications, including but not limited to treatment of:

1. Alzheimer’s disease
2. Anxiety
3. Apathy related to traumatic brain injury
4. Chemical dependence / substance abuse
5. Chronic pain related to spinal cord injury
6. Cognitive dysfunction
7. Depressive symptoms
8. Fibromyalgia
9. Headache
10. Smoking cessation
11. Sleep disturbances
12. Stress related conditions
13. Tinnitus
14. Traumatic brain injury

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo. Treatment of mood disorders (anxiety, depression) and chemical dependency issues require the same level of evidence to ensure valid conclusions regarding superiority over placebo.

Treatment with an electrical stimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an electrical stimulation device should be compared to other forms of conservative therapy such as pain medications. In patients with mood disorders or chemical dependency issues, treatment must be compared with the standard of care: psychotherapy or behavioral therapy, respectively, with or without medication.

Literature Appraisal

Several Cochrane reviews and randomized controlled studies were published on the use of CES for a variety of indications.

Systematic Reviews

- In 2014, Boldt et al. evaluated non-pharmacological interventions for chronic pain in people with spinal cord injury in a Cochrane systematic review, including two trials that assessed the effects of transcranial direct current stimulation (tDCS), three trials that used repetitive transcranial magnetic stimulation (rTMS), and three studies that used cranial electrotherapy stimulation (CES). In all of these trials sham controls were used. For the use of tDCS, the overall evidence for the effectiveness of tDCS in reducing chronic pain in spinal cord injury was scarce and inconclusive. For the use of rTMS, the data from the three studies was inconsistent regarding the treatments effectiveness in reducing chronic pain in this population. The two studies on CES had methodological limitations including selective reporting and imbalances in baseline characteristics between groups, and a third study was inconclusive.

- A 2014 Cochrane systematic review assessed the efficacy and safety of CES as a treatment of acute depression compared to sham or simulated CES treatment. Authors searched for randomized trials of CES in adults aged 18-75 with depressive disorder, however, no studies met inclusion criteria. The authors concluded, “(t)here are insufficient methodologically rigorous
studies of CES in treatment of acute depression. There is a need for double-blind randomized controlled trials of CES in the treatment of acute depression.”

- In 2014, O’Connell and colleagues updated their Cochrane systematic review regarding CES as a treatment for chronic pain.[4] The updated review included 6 studies with 270 subjects and found no statistically significant difference between active stimulation and sham. The authors concluded that CES was not effective in the treatment of chronic pain.

- Another Cochrane systematic review and meta-analysis evaluated the use of CES as a non-invasive treatment for chronic pain.[5] No differences were found in health outcomes when CES was compared with sham in the 3 studies which met the inclusion criteria. The review concluded that all available studies were at risk of bias, and that available data failed to suggest that CES provided a clear benefit over sham treatment.

- A 2009 Cochrane systematic review for treatment of apathy in traumatic brain injury found only one randomized controlled trial which met inclusion criteria for the review.[6] However, the reviewers cautioned against making conclusions from this randomized controlled trial due to the small study size (n=21).

Randomized Controlled Trials (RCTs)

A number of randomized controlled studies explored the efficacy of CES for a variety of conditions not addressed in the Cochrane systematic reviews noted above, including Alzheimer’s disease, smoking cessation, anxiety in patients receiving dental care, preoperative anxiety, chemical dependence, sleep disturbances, fibromyalgia, dysfunctional gait, and tinnitus.[7-16] In addition, several RCTs not included in the reviews above were also identified.[17] Overall, data from these studies were unreliable due to the following limitations:

- Small study populations, less than 100 patients total,[7-13,16,18,19] limited the ability to rule out the role of chance as an explanation of study findings.
- Follow-up of study subjects was over a short period of time, less than 6 months, so the medium and long-term effects of CES treatment remain unknown.[7-13,15,18-20]
- Use of co-therapies such as fibromyalgia medications[12] and antidepressants[17] were allowed but not adequately addressed in the analysis, potentially confounding the findings. In some instances the status of the patients regarding concurrent treatments was not addressed at all.[10,18]
- Randomization methods were not clearly stated[7,10] or weak methods of randomization were used.[12,13] The latter did not provide sufficient evidence to support claims of adequate randomization, such as comparison of the active treatment and sham groups at study baseline.
- The use of flawed data analysis methodologies, such as deleting a subset of patients based on their diagnosis after they had been randomized and treated[10], rendered the study findings unreliable.
- Overall, the trials did not adequately explain the clinical significance of the changes observed in their outcomes of interest.[21]
- The treatment parameters used in the studies varied in their frequency, intensity, duration of individual CES sessions, as well as the overall treatment duration. Only two studies evaluated how changes in treatment parameters influenced the same outcome of interest. They did not find a significant difference between the two, but these studies were subject to other major design flaws.[7,8]
Clinical Practice Guidelines

There are no evidence-based clinical practice guidelines that recommend the use of cranial electrical stimulation devices for the treatment of pain or any other indication.

Summary

There is insufficient evidence to determine the effectiveness of cranial electrostimulation therapy (CES) as a treatment of pain or any other condition. In addition, no evidence-based clinical practice guidelines recommend CES as a treatment for any condition. Therefore, cranial electrostimulation therapy (CES) is considered investigational for all indications.

REFERENCES


**CROSS REFERENCES**

Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83

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