

WellCare Health Plans, Inc.
The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*



WellCare Health Insurance of Illinois, Inc.

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Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

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WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

Cranial Electrotherapy Stimulation

Guideline Number: HS-178

Original Effective Date: 7/1/2010

Revision Date: n/a

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Cranial electrotherapy stimulation*, including home use, is considered experimental and investigational for the treatment of neuropsychological indications (e.g., alcoholism, chemical dependency, dementia, depression, headaches, migraine) or any other indications because its effectiveness has not been established.

Cranial electrical stimulation is also known as:

- Electrosleep
- Electrotherapeutic sleep
- Cerebral electrotherapy
- Transcranial electrotherapy
- Transcerebral electrotherapy
- Craniofacial electrostimulation
- Electric cerebral stimulation
- The Liss Body Stimulator that is used to treat alcoholism

BACKGROUND

A limited number of randomized controlled studies explored the efficacy of CES for a variety of conditions, including Alzheimer's disease, smoking cessation, chronic pain related to spinal cord injury, anxiety in patients receiving dental care, chemical dependence, sleep disturbances, depressive symptoms, fibromyalgia, and tinnitus. Overall, data from these studies are unreliable due to the following limitations:

- Small study populations, less than 100 patients total, limit our 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 medium and long-term effects of CES treatment are unknown.
- Use of co-therapies such as fibromyalgia medications and antidepressants 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.

- Randomization methods were not clearly stated or weak methods of randomization were used. 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.
- Some of the study designs allowed for treatment crossover after a specified wash-out period. As medium- and long-term effects of CES have not been evaluated or established, the appropriate wash-out period is difficult to define. In addition, crossover study populations were not necessarily subject to the same treatment parameters as active groups, undermining valid comparisons.
- 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 (6), renders the study findings unreliable.
- Overall, the trials did not adequately explain the clinical significance of the changes observed in their outcomes of interest.
- 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 looked at how changes in treatment parameters influenced the same outcome of interest. They did not find a significant difference between the two, but this study was subject to other major design flaws.

CODING

Non-Covered CPT® Code

- 64550** Application of surface (transcutaneous) neurostimulator
97032 Application of a modality to 1 or more areas; electrical stimulation (manual) each 15 minutes

Non-Covered ICD-9-CM Procedure Codes

Not applicable

Non-Covered HCPCS® codes

- G0283** Unattended Electrical stimulation, to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

Non-Covered ICD-9-CM Diagnosis Codes

All diagnosis are non-covered

*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

REFERENCES

1. Scherder E, Knol D, van Someren E. et al. Effects of low-frequency cranial electrostimulation on the rest-activity rhythm and salivary cortisol in Alzheimer's disease. *Neurorehabil Neural Repair* 2003;17(2):101-8
2. Scherder EJ, van Tol MJ, Swaab DF. High-frequency cranial electrostimulation (CES) in patients with probable Alzheimer's disease. *Am J Phys Med Rehabil* 2006;85(7):614-8
3. Pickworth WB, Fant RV, Butschky MF et al. Evaluation of cranial electrostimulation therapy on short-term smoking cessation. *Biol Psychiatry* 1997;42(2):116-21
4. Capel ID, Dorrell HM, Spencer EP et al. The amelioration of the suffering associated with spinal cord injury with subperception transcranial electrical stimulation. *Spinal Cord* 2003;41(2):109-17
5. Winick RL. Cranial electrotherapy stimulation (CES): a safe and effective low cost means of anxiety control in a dental practice. *Gen Den* 1999;47(1):50-5
6. Schmitt R, Capo T et al. Cranial Electrotherapy Stimulation as a treatment for anxiety in chemically dependent

persons. *Alcohol Clin Exp Res* 1986;10(2):158-60

7. Rose KM, Taylor AG at al. Effects of cranial electrical stimulation on sleep disturbances, depressive symptoms, and caregiving appraisal in spousal caregivers of persons with Alzheimer's disease. *Appl Nurs Res* 2009;22(2):119-25
8. Lichtbroun AS, Mei-Ming C at al. The treatment of fibromyalgia with cranial electrotherapy stimulation. *J Clin Psychiatry* 1984;45(2):60-1, 62-3
9. Kapkin O, Satar B at al. Transcutaneous electrical stimulation of subjective tinnitus. A placebo-controlled, randomized and comparative analysis. *ORL J Otorhinolaryngol Relat Spec* 2008;70(3):156-61
10. Tan G, Rintala DH at al. Using cranial electrotherapy stimulation to treat pain associated with spinal cord injury. *J Rehabil Res Dev* 2006;43(4):461-74