

Cranial Electrotherapy Stimulation

(e.g. Alpha-Stim, Fisher Wallace Stimulator)

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<u>Effective Date</u>	03/2008
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<u>Coverage Policy</u>	DME 59
<u>Version</u>	5

Member specific benefits take precedence over medical policy. Coverage varies across plans. Coverage varies across plans. Refer to the individual’s benefit plan for coverage details*.

Purpose:

This policy addresses Cranial Electrotherapy Stimulation (e.g. Alpha-Stim, Fisher Wallace Stimulator).

Description & Definitions:

Cranial Electrotherapy Stimulation is a noninvasive, battery operated device for home use that stimulates the brain with short duration, low-amp pulses of direct current via externally placed electrodes.

Criteria:

Cranial Electrotherapy Stimulation (e.g. Alpha-Stim, Fisher Wallace Stimulator) does not meet the definition of medical necessity.

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
K1002	Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
K1017	Monthly supplies for use of device coded at K1016

Document History:

Revised Dates:

- 2022: February
- 2019: October
- 2016: April
- 2015: July, September, November
- 2014: January, April, November
- 2013: March, November
- 2012: May, August, September
- 2011: August, September

Reviewed Dates:

- 2023: January
- 2021: February
- 2020: February
- 2017: December
- 2015: January
- 2012: July
- 2011: July
- 2010: March
- 2009: March

Effective Date:

- March 2008

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2022). Retrieved Dec 13, 2022, from Hayes, Inc:

<https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522cranial%2520electrical%2520stimulation%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:1,%2522size%2522:50%257D,%2522type%2522:%2522all%2>

(2022). Retrieved Dec 13, 2022, from Centers for Medicare and Medicaid Services: <https://www.cms.gov/medicare-coverage-database/search->

results.aspx?keyword=electrical%20stimulation&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance

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Chang, W., Tsou, Y., Chen, Y., & Hung, B. (2022, Feb 09). Cranial Electrotherapy Stimulation to Improve the Physiology and Psychology Response, Response-Ability, and Sleep Efficiency in Athletes with Poor Sleep Quality. Retrieved Dec 16, 2022, from PubMed: <https://pubmed.ncbi.nlm.nih.gov/35206134/>

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Neurological Devices; Reclassification of Cranial Electrotherapy Stimulator Devices Intended To Treat Anxiety and/or Insomnia; Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator Devices Intended To Treat Depression. (2019, Dec 20). Retrieved Dec 16, 2022, from Food and Drug Administration: <https://www.federalregister.gov/documents/2019/12/20/2019-27295/neurological-devices-reclassification-of-cranial-electrotherapy-stimulator-devices-intended-to-treat>

Special Notes:*

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Center for Medicare and Medicaid Services (CMS). Medical Policies may be superseded by National or Local Coverage Determination (Medicare) guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The term DME is defined as equipment which, according to 42 CFR §414.202:

- Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally, is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient's home.

<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=190>

Keywords:

SHP Cranial Electrotherapy Stimulation, SHP Durable Medical Equipment 59, Alpha Stim, Fisher Wallace Stimulator, Cranial Electrotherapy Stimulation, behavioral health, Liss Body Stimulator, Electrosleep Therapy, CES, cerebral electrotherapy, craniofacial electrostimulation, electric cerebral stimulation, electrosleep, electrotherapeutic sleep, transcerebral electrotherapy, transcranial electrotherapy, CES Ultra, transcranial direct current stimulation (tDCS), and cranial alternating current stimulation