

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

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

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).

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[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](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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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 Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan 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 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only

supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; • Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

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