Sentara Health Plans

Medicaid

Electrical Stimulation, DME 07

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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 Electrical Stimulation.

Description & Definitions:

Electrical stimulation devices are made of leads, pads and a control unit. The control unit delivers either a continuous or intermittent low voltage to the site of pain. These include, but are not limited to, the following:

- Bioelectric Nerve Block is a non-invasive therapy that uses electrodes applied to the skin in a painful area on the body. The electrodes are connected to a computer program that send out alternating electrical currents for electrical stimulation to block pain
- H-Wave Stimulators are non-invasive multifunctional electrical stimulation devices (High and/or low frequency delivery) to that stimulate a muscle with electrical impulses.
- Interferential Therapy (IF) Neurostimulator Devices use low frequency electrical stimulation to deliver therapy to a specific body site.
- Microcurrent Electrical Nerve Stimulation Devices send electrical impulses to specific areas of the body.
- Percutaneous electrical stimulation places small needles around indicated painful areas and small doses of electrical current are delivered to the sites.
- Peripheral Nerve Stimulator is a minimally-invasive implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter is connected for transmitting the low frequency electrical pulses.
- Transcutaneous Electrical Joint Stimulation Devices (Bionicare) can be used on various joints to help control pain by using patches connected to the skin and allow low electrical current to flow through.
- Transcutaneous Electrical Nerve Stimulator (TENS unit) is a small device that delivers small doses of electrical current through electrodes on the skin to promote pain relief.

Criteria:

Electrical stimulation is considered medically necessary for **1 or more** of the following devices:

- Transcutaneous Electrical Nerve Stimulator (TENS unit) is considered medically necessary with **1 or more** of the following:
    - Acute post-operative pain with **1 or more** of the following:
        - Initial trial period with **ALL of** the following:
            - Used as an adjunct or alternative to pharmacotherapy
            - Used in the first 30 days after surgery
            - Monitored by the physician to determine the effectiveness of the transcutaneous electrical nerve stimulator in managing the pain
        - Continued treatment with **ALL of the** following:
            - Individual has completed an initial trial period within the first 30 days after surgery
            - Documentation from the physician indicates how often the individual used the transcutaneous electrical unit, the duration of use, and the results
            - Documentation from the physician proving the treatment has significantly alleviated pain and continued treatment would be beneficial over a long period of time
            - The ordering physician must be the attending physician or a consulting physician for the disease or condition
    - Chronic, intractable pain other than low back pain with **ALL of** the following:
        - The presumed etiology of the pain must be a type that is accepted as responding to TENS therapy
        - The pain must have been present for at least three months
        - Other appropriate treatments treatment modalities must have been tried and failed
    - Dysmenorrhea as indicated with **ALL of the** following:
        - Disabling dysmenorrhea
        - Secondary causes of dysmenorrhea have been ruled out (e.g. endometriosis)
        - No response to treatment with non-steroidal anti-inflammatory medications (NSAIDs)
- FDA approved form-fitting garment as durable medical equipment for delivering transcutaneous electrical stimulation as prescribed by a doctor is considered medically necessary for **1 or more** of the following:
    - Individual must have a conductive garment, as indicated by **ALL of** the following:
        - There is a large area or many sites to be stimulated.
        - Stimulation will be delivered so frequently that it is not practical to use conventional items including, but not limited to, wires, electrodes or tapes
    - Individual needs garment for treatment of chronic intractable pain where conventional items would not be accessible.
    - Individual has a medical condition that does not allow for conventional items including, but not limited to, tapes, wires or electrodes.
    - Individual needs to access site under a cast
- Replacement supplies for use with Transcutaneous Electrical Nerve Stimulator (TENS) request
- Percutaneous electrical nerve stimulation (PENS) is considered medically necessary for **1 or more** of the following:
    - Treatment of chronic low back pain secondary to degenerative disc disease for up to a thirty (30) day period as part of a multi-modality rehabilitation program that includes exercise
    - Diabetic neuropathy pain
- Peripheral Nerve Stimulator (PNS) is considered medically necessary for **all of the** following:
    - Individual has chronic, severe neurogenic pain including but not limited to complex regional pain syndrome, neuropathic pain, neuralgias, post-surgical pain for at least three to six months in the region of the nerve being targeted

- Individual has failed conservative, less invasive treatment including but not limited to medications, physical therapy, braces, local injections, TENS, psychological therapy, attempts to cure the underlying condition causing the pain for at least six months
- Individual does not have contraindications to the procedure including but not limited to local infections, surgical/medical /psychological conditions that can adversely impact the procedure
- Individual does not have any substance abuse issues
- Individual has been educated and psychologically prepared following discussion of risks and benefits by the treating physician
- Individual had undergone a successful stimulation trial with greater than or equal to 50% reduction in pain intensity before implantation
- Device is FDA approved.

Peripheral Nerve Stimulator (PNS) is considered medically necessary for **1 or more** of the following

- Placement with **All** of the following:
  - Individual has chronic, severe neurogenic pain including but not limited to complex regional pain syndrome, neuropathic pain, neuralgias, post-surgical pain for at least three to six months in the region of the nerve being targeted
  - Individual has failed conservative, less invasive treatment including but not limited to medications, physical therapy, braces, local injections, TENS, psychological therapy, attempts to cure the underlying condition causing the pain for at least six months
  - Individual does not have contraindications to the procedure including but not limited to local infections, surgical/medical /psychological conditions that can adversely impact the procedure
  - Individual does not have any substance abuse issues
  - Individual has been educated and psychologically prepared following discussion of risks and benefits by the treating physician
  - Individual had undergone a successful stimulation trial with greater than or equal to 50% reduction in pain intensity before implantation
  - Device is FDA approved.
- Removal with or without replacement is considered medically necessary when **1 or more** the following criteria are met:
  - The device malfunctions or breaks and individual continues to meet placement criteria
  - Becomes infected
  - No longer warranted with a documented reason

Electrical Stimulation is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Auricular electrical stimulation
- Auricular electroacupuncture
- Bioelectric Nerve Block (Electroceutical Therapy)
- Blockade of the stellate ganglion using transcutaneous electrical nerve stimulator
- Electro-Acuscope Myopulse Therapy System
- Electro-therapeutic point stimulation (ETPSSM) (Microcurrent point stimulation)
- H-Wave Type Stimulators
- Interferential Therapy (IF) Neurostimulator Devices (e.g., RS Medical TENS Plus, Sequential Stimulation with 4 leads or RS-4i)
- Intramuscular stimulation device
- Microcurrent Electrical Nerve Stimulation Devices (e.g., Algonix, Alpha-Stim 100, Electro-Myopulse 75L, electro-Lyoscope 85P, KFH Energy, MENS 2000-D, MICROCURRENT or Myopulse 75C)
- Percutaneous neuromodulation therapy (PNT)
- Peripheral subcutaneous field stimulation or peripheral nerve field stimulation (PNFS)
- Remote electrical neuromodulation [REN] (Nerivio)
- Sympathetic therapy (Electrical sympathetic stimulation therapy)

- The ReBuilder
- Transcutaneous Electrical Joint Stimulation Devices (TEJSD)
- Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) (Scrambler therapy, Calmare)
- Transcutaneous magnetic stimulation

Transcutaneous electrical nerve stimulators are NOT COVERED for ANY of the following indications:

- Abdominal pain, including pregnancy
- Acute pain (less than three months duration) other than post-operative pain
- In individuals with convulsive disorders of the head and neck
- In individuals with implantable electrical devices such as pacemakers or defibrillators
- Pelvic pain, including labor and delivery
- Temporomandibular joint (TMJ) pain
- To reduce subjective pain intensity during dental procedures

To reduce subjective pain intensity during medical procedures.

Coding:

Medically necessary with criteria:

Coding	Description
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
64999	Unlisted procedure, nervous system
A4542	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
A4595	Electrical stimulator supplies, 2
E0720	Transcutaneous electrical nerve stimulation (TENS) device, 2
E0730	Transcutaneous electrical nerve stimulation (TENS) device, 4

E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the
E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist
E1399	Durable medical equipment, miscellaneous
L8680	Implantable neurostimulator electrode, each
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Considered Not Medically Necessary:

Coding	Description
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
0767T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
0768T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
0769T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, subsequent treatment, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
0783T	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
A4541	Monthly supplies for use of device coded at E0733
A4543	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month

A4544	Electrode for external lower extremity nerve stimulator for restless legs syndrome
A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month
A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
E0732	Cranial electrotherapy stimulation (CES) system, any type
E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
E0721	Transcutaneous electrical nerve stimulator for nerves in the auricular region
E0736	Transcutaneous tibial nerve stimulator
E0737	Transcutaneous tibial nerve stimulator, controlled by phone application
E0743	External lower extremity nerve stimulator for restless legs syndrome, each
E0755	Electronic salivary reflex stimulator (intraoral/noninvasive)
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
S8130	Interferential current stimulator, 2
S8131	Interferential current stimulator, 4
S8930	Electrical stimulation of auricular acupuncture points; each 15

Document History:

Revised Dates:

- 2024: December
- 2024: February
- 2023: February
- 2019: November
- 2016: April
- 2015: July
- 2014: April
- 2013: July
- 2012: November
- 2011: February, March, April, May, June, November
- 2010: June

Reviewed Dates:

- 2022: February
- 2019: October
- 2018: October
- 2017: November
- 2016: July
- 2014: July
- 2012: June
- 2009: May

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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).

(2024, Mar 14). Retrieved Nov 15, 2024, from MCG 28th Edition: https://careweb.careguidelines.com/ed28/index.html

(2024). Retrieved Nov 15, 2024, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=A4540&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance

Garza, I., & Schwedt, T. (2024, Oct 03). Chronic migraine. Retrieved Nov 15, 2024, from UpToDate: https://www.uptodate.com/contents/chronic-migraine?search=headache%20treatment&source=search_result&selectedTitle=6%7E150&usage_type=default&display_rank=6#H634848644

Nerivio (Theranica Bio-Electronics Ltd.) for Treatment of Acute Migraine Episodes. (2024, Jun 30). Retrieved Nov 15, 2024, from Hayes - a symplr company: https://evidence.hayesinc.com/report/eer.nerivio4838

Nerivio (Theranica Bio-Electronics, Ltd.) Remote Electrical Neuromodulator for Treating Migraine. (2022, May). Retrieved Nov 15, 2024, from ECRI - Clinical Evidence Assessment: https://home.ecri.org/pages/ecri-clinical-evidence-assessment-solution

Nerivio Migra. (2018, Nov 06). Retrieved Nov 15, 2024, from U.S. Food and Drug Administration: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180059.pdf

Provider Manual Title: Durable Medical Equipment - Chapter IV: Covered Services and Limitations. (2024, Oct 24). Retrieved Nov 15, 2024, from Department of Medical Assistance Services - MES Public Portal: https://vamedicaid.dmas.virginia.gov/sites/default/files/2024-10/DME%20Chapter%20IV%20%28updated%2010.24.24%29_Final.pdf

The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. (2021, Jun 23). Retrieved Nov 18, 2024, from American Headache Society: https://headachejournal.onlinelibrary.wiley.com/doi/10.1111/head.14153

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 by 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 Electrical Stimulation, SHP Durable Medical Equipment 07, Transcutaneous Electrical Nerve Stimulator, TENS unit, SHP DME 07, TENS, transcutaneous electrical stimulation, therapeutic electrical nerve stimulation, SHP Durable Medical Equipment 07, Bioelectric Nerve Block, electric current, brain, pain, electroceutical therapy, Bioelectric therapy, non-invasive neuron blockade, electroceutical neuron blockade, bioelectric treatment system, nerve conduction block, SHP H-Wave Type Stimulators, electrical impulse, pain relief, increase blood circulation, lymphatic drainage, range of motion, muscle spasms, atrophy, SHP Interferential Therapy (IF) Neurostimulator Devices, low frequency electrical stimulation, pain, muscle spasms, muscle strain, physical therapy, RS Medical TENS Plus, Sequential Stimulation with 4 leads, RS-4i, BioStim® INF, INF Plus™, Endomed Interferential Stimulators, Flex-IT™, Soleo Galva Electrotherapy System, IF 4000, IF 8000, FastStart® IF, OrthoStim4™, SurgiStim4™, VQ™ Vector, RSJ, RS JC, RS-4i® Sequential Stimulator; RS-2i® Interferential Stimulator, Stereodynator®, PRO ElecDT® 2000, Vectorsurge 5 Model 470, interferential current (IFC), IFT, SHP Microcurrent Electrical Nerve Stimulation Devices, electrical impulse, pain, healing, analog device, SHP Percutaneous Electrical Nerve Stimulation, PENS, chronic low back pain, degenerative disc disease, exercise, SHP Transcutaneous Electrical Joint Stimulation Devices, TEJSD, SHP Durable Medical Equipment 227, electrical impulses, brace, BioniCare Knee System, OActive Knee Brac), BIO-1000™ System, Diatermed II, OrthoCor™ Active Knee System™, neoGEN-Series® system, SofPulse®, SofPulse® 912-M10, Roma3™, Torino II™, StimRouter Neuromodulation System, Peripheral Nerve Stimulation, Electro-Acuscope Myopulse Therapy System, DyAnsys auricular electrical nerve stimulator