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Subject: Transcutaneous Electric Nerve Stimulation (TENS)

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DESCRIPTION:

TENS devices consist of an electrical pulse generator, usually battery-operated, connected by wire to 2 or more electrodes, which are applied to the surface of the skin at the site of the pain. Since 1977, a large number of devices have received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) process. Marketing clearance via the 510(k) process does not require data regarding clinical efficacy; these devices are considered substantially equivalent to predicate devices marketed in interstate commerce prior to May 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified and do not require approval of a premarket approval application (PMA).

The BioniCare Bio-1000™ stimulator is a device that has received U.S. Food and Drug Administration (FDA) 510(k) marketing clearances to deliver pulsed electrical stimulation for the treatment of osteoarthritis of the knee and rheumatoid arthritis of the hand. The FDA gave the BioniCare Bio-1000™ clearance after finding it to be substantially equivalent to transcutaneous electrical nerve stimulation devices. The BioniCare system consists of an electronic stimulator device with electrical leads that are placed over the affected area and held in place with a lightweight, flexible wrap and Velcro fasteners. The battery-powered device delivers small pulsed electrical currents of 0.0 to 12.0 volt output. It is recommended that the device be worn for at least 6 hours per day and patients are reported to often wear the device while sleeping. The BioniCare system is contraindicated in patients with demand-type pacemakers and may interfere with other electronic devices.

The ReBuilder® stimulator is a device that has received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance as a prescription device for the following uses: relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle reeducation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, maintaining or

increasing range of motion, symptomatic relief of chronic intractable pain, and post-traumatic and post-surgical pain relief. The FDA found the ReBuilder® to be substantially equivalent to transcutaneous electrical nerve stimulation (TENS) devices. The ReBuilder® system consists of an electrical stimulator with lead wires that may be used with conductive garments (gloves, socks or a sleeve), and/or a footbath. The conductive garments are moistened with water and an electrolyte solution. If the footbath is used, the electrolyte solution is added to the water. The ReBuilder® features analysis of waveforms through its internal microprocessor.

Interferential stimulation (IFS) is a type of electrical stimulation. It is believed that IFS permeates the tissues more effectively and thus is more comfortable than transcutaneous electrical nerve stimulation (TENS). Interferential stimulation has been investigated as a technique to reduce pain, improve range of motion, or promote local healing following various tissue injuries.

Interferential stimulation (IFS) uses paired electrodes of 2 independent circuits carrying high-frequency (4,000 Hz) and medium-frequency (150 Hz) alternating currents. The superficial electrodes are aligned on the skin around the affected area. It is believed that IFS permeates the tissues more effectively and, with less unwanted stimulation of cutaneous nerves, is more comfortable than transcutaneous electrical stimulation (TENS). There are no standardized protocols for the use of interferential therapy; the therapy may vary according to the frequency of stimulation, the pulse duration, treatment time, and electrode-placement technique.

Microcurrent therapy (MCT) [microcurrent electrical nerve stimulation (MENS)] delivers significantly reduced electrical stimulation compared to TENS, using current between 1 and 1,000 microA, It is most commonly delivered with hand-held probes or self-adhesive electrodes that bracket the treated area. While TENS blocks pain, MCT acts on the naturally occurring electrical impulses to decrease pain by stimulating the healing process. Examples of this type of device include, but are not be limited to, Accutron, Algonix, Alpha-Stim 100, Electro-Lyoscope 85P, Electro-Myopulse 75L, KFH Energy, MENS 2000-D, MICROCURRENT and Myopulse 75C.

Combination electrical stimulation devices use a combination of different stimulation modalities, such as combining TENS with interferential current (IFC), TENS with ultrasound, TENS with low level laser therapy (LLLT) and/or light-emitting diode (LED) therapy, or TENS with neuromuscular stimulation (NMES).

External or transcutaneous trigeminal nerve stimulation (TNS) is a non-invasive therapy that has been investigated as treatment for a variety of conditions, including attention deficit hyperactivity disorder (ADHD), depression, epilepsy, and headache. TNS delivers signals to the brain via the trigeminal nerve.

POSITION STATEMENT:

Transcutaneous electrical nerve stimulators (TENS)

Transcutaneous electrical nerve stimulator (TENS) **meets the definition for medical necessity** for the following indications:

- Acute post-operative pain
- Chronic, intractable pain where other treatment modalities have been tried and failed.

Continued TENS use requires validation of medical necessity based on documentation of effectiveness by the treating physician.

Conductive Garments

A conductive garment (E0731) used with a TENS unit **meets the definition of medical necessity** when the conductive garment is FDA approved, prescribed by a physician, and when one or more of the following conditions exist:

- Has a large area or multiple sites to be stimulated and the stimulation would have to be delivered so frequently that pain cannot be managed by using conventional electrodes, adhesive tapes and lead wires
- Chronic intractable pain is located in areas that are inaccessible with the use of conventional electrodes
- Has a medical condition (i.e., skin condition) that prevents the use of conventional electrodes
- Requires electrical stimulation beneath a cast
- Has a medical need for rehabilitation strengthening following an injury where the nerve supply to the muscle is intact.

Replacement TENS Criteria:

Purchased DME Criteria:

- New MD Order for Replacement Device/Item (would demonstrate continued medical need), **AND**
- DME is malfunctioning, non-repairable, and out-of-warranty, **OR** replacement is needed due to growth or change of condition, **AND**
- Cost to repair DME exceeds cost of a replacement DME

Repair/Replacement Exclusions:

- Replacement or repair of an item that has been misused or abused by the user or caregiver will be the responsibility of the user:
    - This includes DME that was sold/discarded/loaned to other parties
    - Lost/stolen DME is reviewed on case-by-case basis
- Replacement DME for the purposes of upgrading technology **does not meet the definition of medical necessity**

TENS is considered **experimental or investigational**, as there is insufficient clinical evidence to support the use of TENS for the following indications:

- Pain relief for labor and vaginal delivery
- Management of nausea and vomiting of pregnancy
- Management of postoperative-induced or chemotherapy-induced nausea and vomiting
- Abdominal pain

- Pelvic pain
- Acute and chronic headache
- Depression
- Epilepsy
- Attention deficit hyperactivity disorder (ADHD)

There is insufficient scientific evidence to permit conclusions regarding the effects of TENS in the treatment of the above indications, on health outcomes.

Electrical/electromagnetic stimulation (e.g. Bionicare) for the treatment of osteoarthritis or rheumatoid arthritis is considered **experimental or investigational**. There is insufficient evidence to indicate the use of electrical/electromagnetic stimulation for the treatment of arthritis will result in improvements in health outcomes.

The ReBuilder® system **does not meet the definition of medical necessity,** as there is insufficient published clinical evidence that demonstrates this device is more effective than standard TENS devices.

Interferential stimulation (IFC, ICS or IFS)

Interferential current stimulation is considered **experimental or investigational** for treatment of pain. The available scientific evidence remains insufficient to permit conclusions concerning the effect of this technology on net health outcomes.

Microcurrent electrical nerve stimulation (MENS)

Microcurrent electrical nerve stimulation (e.g., Accutron, Algonix, Alpha-Stim 100, Electro-Lyoscope 85P, Electro-Myopulse 75L, KFH Energy, MENS 2000-D, Myopulse 75C) is considered **experimental or investigational** for treatment of pain. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

Combination or sequential electrical stimulation therapy

Combination or sequential electrical stimulation devices (e.g., NexWave, Neufit Neubie, Flex-MT+, RS-4i, EMSI TENS/EMS-14, Kneehab XP, Empi Phoenix, QB1, Neurolumen, InTENsity Select, UltraTENS) are considered **experimental or investigational** for any indication. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

External trigeminal nerve stimulation therapy (eTNS)

External or transcutaneous (non-implantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®, Smile eTNS) are considered **experimental or investigational** for all indications, including but not limited to treatment of attention deficit hyperactivity disorder (ADHD), epilepsy, headache, and depression. There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding

0766T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve (**investigational**)
0767T	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, 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) (**investigational**)

HCPCS Coding:

A4541	Monthly supplies for use of device coded at E0733 **(investigational)**
A4556	Electrodes (e.g., apnea monitor), per pair
A4557	Lead wires (e.g., apnea monitor), per pair
A4558	Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz
A4595	Transcutaneous electrical nerve stimulation (TENS) device supplies, 2 lead, per month
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
E0720	Transcutaneous electrical nerve stimulator (TENS) device, two lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS
E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve **(investigational)**
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories (**investigational**)
E0765	FDA-approved nerve stimulator, with replacement batteries, for treatment of nausea and vomiting
S8130	Interferential current stimulator, 2-channel **(investigational)**
S8131	Interferential current stimulator, 4-channel **(investigational)**

REIMBURSEMENT INFORMATION:

Supplies for Rented TENS Units

The reimbursement for supplies used with a rented TENS unit is included in the rental allowance and includes the following:

- Electrodes (any type) (A4556)
- Conductive past or gel (if needed, depends on the type of electrode used) (A4558)
- Tape or other adhesive (if needed) (A4364)
- Adhesive removal, skin preparation materials (A4455)

- Batteries (9 volt or AA, single use or rechargeable) (A4630)
- Battery charger (if rechargeable batteries are used).

Supplies for Purchased TENS Units

If the TENS unit (E0720 or E0730) is purchased, the initial allowance includes lead wires and one month's supply of electrodes, conductive paste or gel (if needed), and batteries.

A separate allowance is made for medically necessary replacement supplies used with a purchased TENS unit. Reimbursement for TENS supplies is limited to one unit of A4595 per month for a 2-lead TENS and two units of A4595 per month for a 4-lead TENS.

Replacement of electrodes (A4556) is limited to four (4) units per month.

Replacement of damaged lead wires (A4557) is rarely medically necessary more frequently than every 12 months; therefore, reimbursement for code A4557 is limited to one (1) unit per 12-month period.

Replacement of the battery (A4630) is limited to one (1) unit per month.

Reimbursement for A4595 includes the following:

- Electrodes (any type) (A4556)
- Conductive past or gel (if needed, depends on the type of electrode used) (A4558)
- Tape or other adhesive (if needed) (A4364)
- Adhesive removal, skin preparation materials (A4455)
- Batteries (9 volt or AA, single use or rechargeable) (A4630)
- Battery charger (if rechargeable batteries are used).

Other Supplies

No separate or additional reimbursement is made for the following supply items:

- Adapters (i.e., snap, banana, alligator, tab, button, clip)
- Belt clips
- Adhesive remover
- Additional connection cable for lead wires
- Carrying pouches or covers.

Services in excess of these limitations require documentation of medical necessity (e.g. a new condition or injury: an extended interruption in treatment).

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, treatment plan, and radiology reports (if applicable).

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative

Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Radiology report	18726-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products:

The following National Coverage Determinations (NCDs) located at www.cms.gov were reviewed on the last guideline reviewed date:

- Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)
- Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2)
- Electrical Nerve Stimulators 160.7
- Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)
- Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) Neuromuscular Electrical Stimulation (NMES) (160.13)
- Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27)

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) located at www.cms.gov was reviewed on the last guideline reviewed date:

- Transcutaneous Electrical Nerve Stimulators (TENS) (L33802)
- Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L34821)

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

TENS (transcutaneous electric nerve stimulation): a small battery powered electronic device used for the treatment of pain. An electrode attaches to the skin near the painful area and sends a signal to the brain that competes with "pain signals" from the painful area, resulting in less perception of pain by the brain. These devices do not treat the cause of the pain, but decreases the brain's sensation of the pain.

PENS (percutaneous electric nerve stimulation): similar to TENS except that instead of electrodes attached to the skin, a needle is inserted into the site of pain.

RELATED GUIDELINES:

Diagnosis and Treatment of Temporomandibular Joint Disorder, 02-20000-12
Percutaneous Electrical Nerve Stimulation (PENS), 02-61000-03

OTHER:

None applicable.

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6. Blue Cross Blue Shield Association Evidence Positioning System®. 1.01.24 - Interferential Current Stimulation, 07/23.
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14. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Treatment of Motor Function Disorders with ELECTRIC NERVE STIMULATION (160.2) (04/01/03).
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/28/23.

GUIDELINE UPDATE INFORMATION:

09/15/02	Medical Coverage Guideline Reformatted and Revised.
01/01/03	HCPCS coding update.
08/15/03	HCPCS coding update consisting of the addition of code E0765.
11/15/03	Review and revision of guideline consisting of updated references.
01/01/04	Annual HCPCS coding update.
09/15/04	Unscheduled review and revision of guideline; consisting of updated references, and various formatting changes; information on Bionicare device added.
03/15/05	Revision of guideline; consisting of addition of EMSI IF-5000.
01/01/06	Annual HCPCS update consisting of the addition of E0762 and the revision of A4630.
08/15/06	Scheduled review and revision of guideline consisting of updated references.
01/01/07	HCPCS coding update consisting of the revision of A4558, E0720 and E0730.
07/15/07	Annual review, current coverage and limitations maintained, reformatted guideline, references updated.
07/15/08	Review and revision of guideline consisting of updated references.
06/15/09	Scheduled review; no change in position statement. Update references.
01/01/10	Annual HCPCS coding update: remove reference to HCPCS code A4365.

04/15/10	Annual review; no change in position statement. Update references.
05/15/10	Review with revision to position statement to add nausea and vomiting of pregnancy as an experimental or investigational use for electric stimulation. References updated.
09/15/11	Revision; formatting changes.
02/15/12	Annual review; added coverage statement for interferential stimulation (E/I). Updated description section, CPT coding section, HCPCS coding section, reimbursement information and references.
11/15/12	Revision; revised reimbursement section regarding code 64550.
05/15/13	Revision; revised description section and position statement. Updated references.
09/15/15	Revision; updated Reimbursement Information section.
01/01/18	Annual CPT/HCPCS coding update: added 64550.
01/01/19	Annual CPT/HCPCS coding update. Deleted 64550.
08/15/19	Scheduled review. Revised description and program exceptions. Added coverage statement (E/I) for microcurrent electrical nerve stimulation. Updated references.
08/15/20	Scheduled review. Added coverage criteria for replacement units. Updated references.
09/15/21	Scheduled review. Maintained position statement and updated references.
01/01/23	Annual CPT/HCPCS coding update. Added 0766T, 0767T, 0768T, 0769T.
05/25/23	Update to Program Exceptions section.
10/15/23	Scheduled review. Revised description. Added coverage statements for combination and sequential stimulators, and external trigeminal nerve stimulators. Added codes K1016, K1017. Updated references.
01/01/24	Annual CPT/HCPCS coding update. Added A4541, E0733; revised 0766T, 0767T; deleted 0768T, 0769T, K1016, K1017.