Electrical Stimulation Devices and Therapies (Formerly Electrical Stimulators-Neuromuscular/Functional)

Policy Number:	**M20130117012**
Effective Date:	**4/1/2013**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus; ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for electrical stimulation devices and therapies.

Policy:

Background:

Electrical stimulators provide direct, alternating, pulsating and/or pulsed wave energy to accelerate healing of chronic wounds, facilitate functional restoration, treat muscle atrophy and diminish pain. Neuromuscular Electrical Stimulation (NMES), Transcutaneous Electrical Nerve Stimulation (TENS), and Electromagnetic Therapy (ET) are some of the many forms of electrical stimulation that may be provided by indwelling transcutaneous needles or by surface electrodes.
Various devices and treatments are available for patients in an outpatient clinic, a physician's office, or in the patient's home. Some treatments may require surgical implantation of leads and a trial period to ensure efficacy. Electrical stimulation for some conditions may be tried as a last resort when the customer has failed a trial of conservative therapies.

Neuromuscular Electrical Stimulation (NMES): Coverage of an NMES for more than two months is determined by individual consideration based upon supportive documentation (including current muscle testing) provided by the therapist and/or attending physician.

Functional Electrical Stimulation in Patients with Spinal Cord Injury (SCI): The type of NMES that is used to enhance the ability to walk of spinal cord injury (SCI) patients is commonly referred to as functional electrical stimulation (FES).

Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Pain and Chronic Low Back Pain (CLBP): A four lead TENS unit may be used with either two leads or four leads, depending on the characteristics of the member's pain. If it is ordered for use with four leads, the medical record must document why two leads are insufficient to meet the member's needs; and if two TENS leads are reasonable and necessary, then a maximum of one unit of Code A4595 would be allowed per month; if four TENS leads are necessary, a maximum of two units per month would be allowed. If the use of the TENS unit is less than daily, the frequency of billing for the TENS supply code should be reduced proportionally.

Conductive Garment for use with a TENS or an NMES device during the trial period is only covered if the member has a documented skin problem prior to the start of the trial period or the TENS or NMES is reasonable and necessary for the member.

Commercial and Self-Funded: electrical stimulation devices and therapies may be covered utilizing the criteria below.

Medicare Advantage:

There is currently a National Coverage Determination (NCD) for neuromuscular electrical stimulation There are National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) for conductive garments used with transcutaneous electrical nerve stimulation (TENS) units. There is a National Coverage Determination (NCD) for non-implantable pelvic floor electrical stimulators. There is a National Coverage Determination (NCD) for supplies used in the delivery of transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation There is a National Coverage Determination (NCD) for electrical stimulation (ES) and electromagnetic therapy for the treatment of wounds. There is a Local Coverage Determination (LCD) for posterior tibial nerve stimulation for voiding

dysfunction. There is a Local Coverage Determination (LCD) for transcutaneous electrical joint stimulation devices (TEJSD). Please refer to the links listed in the Reference section for Medicare Advantage members. In the absence of CMS criteria, the commercial criteria below will be utilized.

MediSource, MediSource Connect, Child Health Plus and Essential Plan: covers electrical stimulators utilizing New York state Medicaid criteria and the criteria below. Please refer to the links listed in the Reference section.
TENS units (E0730) are limited to the diagnosis codes per the emedny DME provider manual.
Members with a diagnosis of knee pain due to osteoarthritis. Reimbursable ICD codes are limited to: M17.0, M17.11, M17.12, M17.2, M17.31, M17.32, M17.4, and M17.5. The codes may be billed in conjunction with E0730: A4556, A4557 and A4630.
TENS and FES units that are billed with a covered diagnosis must also meet the applicable medical necessity criteria within this policy for that diagnosis.

Clinical Indications

Electrical Stimulation Devices and Therapies may be covered for **ALL** of the following:

- Medical record documentation must include **ALL** of the following:
    - The exact nature of the member's impairments and functional limitations to be treated
    - Medical necessity for the type, frequency and duration of therapy to treat the member's condition
    - Appropriate conservative therapies that have been tried and failed e.g., pharmacological, surgical, physical, or psychological therapies
    - The expected goals for medically necessary therapy(s)
    - When regression or plateaus occur, the reasons for the lack of progress should be noted to justify continued treatment OR no regression or plateaus have occurred
- **1 or more** of the following:
    - Neuromuscular electrical stimulation (NMES) will be covered as a rental only, when used as one component of a comprehensive rehabilitation program for the treatment of disuse atrophy where the nerve supply to the muscle is intact for **1 or more** of the following:
        - Brain
        - Spinal cord
        - Peripheral nerves
        - Other non-neurological reasons for disuse atrophy such as **1 or more** of the following:
            - Casting or splinting of limb
            - Contracture due to scarring of soft tissue, as in burn lesions
            - Major knee surgery (e.g., ACL, TKR)
            - Total hip replacement (THR) surgery (until orthotic training begins)
    - Functional Electrical Stimulation (FES) is limited to spinal cord injury (SCI) patients for walking with **ALL** of the following:
        - Completion of a training program which consists of at least 32 physical therapy sessions with the device over a period of three (3) months. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program. The goal of physical therapy

must be to train SCI patients on the use of FES devices to achieve walking, not to reverse or retard muscle atrophy
        - Intact lower motor units (L1 and below) (both muscle and peripheral nerve)
        - Muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently
        - Members who have demonstrated brisk muscle contraction to FES and have sensory perception electrical stimulation sufficient for muscle contraction
        - Members that possess high motivation, commitment and cognitive ability to use such devices for walking
        - Member can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes
        - Demonstrated hand and finger function to manipulate controls
        - At least six-month post recovery spinal cord injury and restorative surgery
        - Member without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis
        - Demonstrated willingness to use the device long-term
    - Transcutaneous Electrical Nerve Stimulation (TENS) for **1 or more** of the following:
        - Acute Post-operative Pain and **1 or more** of the following:
            - Medical necessity is limited to 30 days from the day of surgery
            - Coverage for more than 30 days is determined by individual consideration based upon supportive documentation provided by the attending physician
        - Chronic Pain and **ALL** of the following:
            - The medical record must document the location of the pain, the duration of time the patient has had the pain, and the etiology of the pain
            - The pain must have been present for at least 90 days
            - The etiology of the pain must be a type that is accepted as responding to TENS therapy. Examples of conditions for which a TENS unit is not considered to be reasonable and necessary are: headache, visceral abdominal pain, pelvic pain, and temporomandibular joint (TMJ) pain (not all inclusive)
            - The TENS unit must be used by the member on a trial basis for a minimum of 30 days, but not to exceed 60 days. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain
            - The physician must determine that the member is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. The physician's records must document a re-evaluation of the member at the end of the trial period, must indicate how often the member used the TENS unit, the typical duration of use each time, and the results
            - The physician ordering the TENS unit must be the attending physician or a consulting physician for the disease or condition resulting in the need for the TENS unit
        - Chronic Low Back Pain (CLBP) and **1 or more** of the following:

- The member has **1 or more** of the following diagnoses:
  - Lumbosacral root lesions, not elsewhere classified
  - Sacroiliitis, not elsewhere classified
  - Lumbosacral spondylosis without myelopathy
  - Thoracic or lumbar spondylosis with myelopathy – lumbar region
  - Lumbar intervertebral disc without myelopathy
  - Lumbosacral intervertebral disc
  - Intervertebral disc disorder myelopathy – lumbar region
  - Post laminectomy syndrome – lumbar region
  - Other and unspecified disc disorders, lumbar region
  - Spinal stenosis, lumbar region without neurogenic claudication
  - Spinal stenosis, lumbar region with neurogenic claudication
  - Lumbago
  - Sciatica
  - Thoracic or lumbosacral neuritis or radiculitis, unspecified, radicular
  - Syndrome of lower extremities
  - Acquired spondylolisthesis
  - Non-allopathic lesions NEC (not elsewhere classified) – lumbar region
  - Spondylosis, lumbosacral region
  - Spondylolisthesis
  - Fracture of vertebral column without mention of spinal cord injury, lumbar, closed
  - Fracture of vertebral column with mention of spinal cord injury, lumbar, closed
  - Sprains and strains of sacroiliac region – lumbosacral (joint) (ligament)
  - Sprains and strains of sacroiliac ligament
  - Sprains and strains of other and unspecified parts of back, lumbar
  - Injury to nerve roots and spinal plexus, lumbar root
- The TENS unit must be used by the member on a trial basis for a minimum of 30 days, but not to exceed 60 days. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain
- The physician must determine that the member is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. The physician's records must document a re-evaluation of the member at the end of the trial period, must indicate how often the member used the TENS unit, the typical duration of use each time, and the results
- The physician ordering the TENS unit must be the attending physician or a consulting physician for the disease or condition resulting in the need for the TENS unit

- Conductive Garment for use with Transcutaneous Electrical Nerve Stimulation (TENS) may be covered when **ALL** of the following conditions are met:
    - It has been prescribed by a physician for use in delivering covered TENS treatment
    - **1 or more** of the medical indications outlined below is met:
        - The member cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires
        - The member cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires
        - The member has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires
        - The patient requires electrical stimulation beneath a cast to treat chronic intractable pain
- Conductive Garment for use with a neuromuscular electrical stimulator (NMES) may be covered when there is a skin disease or a cancer at the area of stimulation
- Non-Implantable Pelvic Floor Electrical Stimulator is covered for the treatment of stress and/or urge urinary incontinence for **ALL** of the following:
    - Cognitively intact members
    - Members who have failed a documented trial of pelvic muscle exercise (PME) training. A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing four weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.
- Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds are considered adjunctive therapies and will only be covered when **ALL** of the following criteria have been met:
    - Electrical Stimulation (ES) and electromagnetic therapy will be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence
    - Appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute. Standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a member with pressure ulcers (usually every 2 hours), offloading of pressure and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of

a compression system for members with venous ulcers. Measurable signs of improved healing include: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue
    - Electrical Stimulation (ES) and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or a clinician incident to a physician service
- Initial Tumor Treatment Field Therapy (TTFT) is covered when **ALL** of the following criteria are met:
    - The member has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, Glioblastoma Multiforme (GBM)
    - The member has received initial treatment with maximal debulking surgery, followed by chemotherapy and radiotherapy
    - Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy, whichever is later
    - The member has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria
    - The member has a Karnofsky Performance Score (KPS) of at least 70
    - The member will use tumor treatment field therapy (TTFT) for an average of 18 hours per day
    - The member is 22 years or older and not pregnant
    - Absence of intracranial shunt or other implanted intracranial device
- Continued coverage of Tumor Treatment Field Therapy beyond the first three months of therapy requires **ALL** of the following:
    - That no sooner than the 60th day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is continuing to use and is benefiting from TTFT.
    - Documentation of clinical benefit is demonstrated by re-evaluation by the treating provider

Objective evidence of adherence to therapy, defined as an average usage of 18 hours per day
Per New York State criteria for State product members, MediSource, MediSource Connect, Child Health Plus and Essential Plan will continue to cover electrical stimulators if medically necessary for **1 or more** of the following:

- For those patients with electrodes and/or stimulators implanted prior to October 1, 2013, Medicaid will continue to cover the devices and supplies, and provide reimbursement to replace/revise/remove devices as medically necessary, regardless of patient diagnosis
- Diaphragmatic/phrenic pacing device and related services and supplies
- Vagus nerve stimulator device and related services and supplies
- Sacral nerve stimulator device and related services and supplies

For Commercial and Self-Funded members, **NOT COVERED** for **ANY** of the following:

- Functional electrical stimulation for walking will not be covered in spinal cord injury (SCI) patients with cardiac pacemakers
- Functional electrical stimulation for walking will not be covered in spinal cord injury (SCI) patients severe scoliosis or severe osteoporosis

- Functional electrical stimulation for walking will not be covered in spinal cord injury (SCI) patients with skin disease or cancer at area of stimulation
- Functional electrical stimulation for walking will not be covered in spinal cord injury (SCI) patients with irreversible contracture
- Functional electrical stimulation for walking will not be covered in spinal cord injury (SCI) patients with autonomic dysflexia
- Functional electrical stimulation devices for use in members without spinal cord injury are considered investigational
- Functional electrical stimulation exercise devices (i.e., RT300 Electrical Stimulation Bike) are considered investigational
- Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) for the treatment of chronic low back pain, including, but not limited to, diabetic neuropathy, headache, and osteoarthritis of the knee. The evidence in the peer-reviewed literature did not demonstrate Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) is effective in the long term and therefore is considered investigational
- Transcutaneous Electrical Nerve Stimulation (TENS) for the treatment of post-operative nausea and vomiting, chemotherapy induced nausea, nausea and vomiting of pregnancy, motion sickness and all other indications are not covered, considered investigational
- Threshold electrical stimulation (TES) as a treatment for motor disorders, including, but not limited to, cerebral palsy, scoliosis, or spina bifida is considered investigational
- Interferential stimulators for the treatment of circulation disorders, range of motion, edema, muscle spasms, bone healing, and pain and to promote soft tissue healing are considered investigational
- Gastric electrical stimulation for the treatment of obesity is considered investigational
- Transcutaneous electrical joint stimulation devices are considered investigational for any indication
- Implantable pulse generators, radiofrequency devices, or leads for peripheral occipital nerve stimulation to treat occipital neuralgia or headaches, are not approved by the FDA
- Electrosleep therapy for the treatment of chronic insomnia, anxiety, depression, psychosomatic disorders, such as asthma, spastic colitis, or tension headache, and for organic disorders including essential hypertension
- Electrical aversion (electroversion) therapy for the treatment of alcoholism
- Electrical continence aids which stimulate anal musculature to allow the member to ambulate without incontinence
- Electrical stimulation used in the treatment of Bell's palsy, multiple sclerosis and strokes when there is no potential for restoration of function
- Scrambler therapy MC-5A CALMARE® (Transcutaneous Electrical Modulation Pain Reprocessing Device) for chronic, intractable pain, post-surgical pain, post-traumatic acute pain, cancer related pain, and reducing peripheral neuropathy caused by chemotherapy
- Electrical stimulation of muscles for treatment of scoliosis
- Cefaly device for prevention, treatment and other indications for migraine headaches is not covered. There is insufficient evidence in the peer-reviewed literature to support the use of the Cefaly transcutaneous electrical stimulator (TENS) headband for the treatment of migraine headaches, therefore the Cefaly device is considered investigational and not covered

- GammaCore non-implantable transcutaneous vagus nerve stimulation (tVNS) is considered investigational because the long-term outcomes in the published peer-reviewed scientific literature do not support the safety and effectiveness for the acute or chronic treatment of pain associated with episodic cluster headache or migraines in adults
- Cranial Electrotherapy Systems (CES) that deliver low level electrical stimulation (microcurrent) to the brain through electrodes that are attached to the ear lobes or behind the ears as proposed treatment of anxiety, depression, insomnia, substance abuse, depression, tension headaches, cluster headaches and migraines are investigational and not covered for any indication. There is insufficient evidence regarding the safety and effectiveness of Cranial Electrotherapy Systems (CES) for the reduction of pain or improvement in function
- Remote electrical neuromodulation (REN) (e.g. Nerivio) device proposed as a treatment for episodic or chronic migraine headaches is considered investigational and not covered for all indications because there is insufficient evidence regarding the safety and effectiveness of REN
- Cala Trio nerve stimulating device (E0734, A4542) proposed as a treatment of essential tremors is considered experimental and investigational because there is insufficient evidence regarding the safety and effectiveness has not been established
- Monarch external trigeminal nerve stimulation (eTNS) proposed for treatment of pediatric ADHD is considered experimental and investigational because there is insufficient evidence regarding the safety and effectiveness has not been established
- Electrical stimulation of muscles for treatment of scoliosis (HCPCS E0744) is considered experimental and investigational because there is insufficient evidence regarding the safety of and effectiveness for this treatment has not been established
- Biofeedback devices are not covered for home use because they are considered experimental and investigational as there is insufficient evidence in peer-reviewed medical literature regarding effectiveness or proof the technology improves outcomes
- The eXciteOSA Daytime Therapy Device for the treatment of obstructive sleep apnea is considered to be experimental and investigational as there is insufficient evidence in peer-reviewed medical literature regarding safety, effectiveness and/or proof the technology improves outcomes
- The NTX100 Tonic Motor Activation (TOMAC) System for the treatment of restless leg syndrome is considered to be experimental and investigational as there is insufficient evidence in peer-reviewed medical literature regarding safety, effectiveness and/or proof the technology improves outcomes
- The use of auricular stimulation for, but not limited to, the treatment of opioid withdrawal (e.g., Sparrow Ascent) is considered to be experimental and investigational as there is insufficient evidence in peer-reviewed literature regarding the safety, effectiveness, and/or proof that the technology improves outcomes
- Electrical Stimulation (ES) or electromagnetic therapy for wounds that demonstrate a 100% epithelialized wound bed
- Electrical Stimulation (ES) or electromagnetic therapy for wounds, if measurable signs of healing have not been demonstrated within any 30-day period of treatment
- Unsupervised use of Electrical Stimulation (ES) or electromagnetic therapy for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary
- Tumor treatment field therapy will be denied as not reasonable and necessary for the treatment of recurrent Glioblastoma Multiforme (GBM)

For State product members, **NOT COVERED** for **ANY** of the following:

- Functional electrical stimulation (FES) for spinal cord and head injury
- Functional electrical stimulation (FES) for cerebral palsy
- Functional electrical stimulation (FES) for upper motor neuron disease, including Parkinson's disease, late effects of acute poliomyelitis, anterior horn cell diseases, or multiple sclerosis

Pre-Authorization Required? Yes ☒ No☐

Definitions

Neuromuscular electrical stimulation (NMES) involves the use of a device that transmits an electrical impulse to activate muscle groups by way of electrodes. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients.

Autonomic dysreflexia: a syndrome affecting persons with a spinal cord lesion above the midthoracic level (tetraplegics and some paraplegics) that is characterized by hypertension, bradycardia, severe headaches, pallor below and flushing above the cord lesions, and convulsions. It is the result of impaired function of the autonomic nervous system caused by simultaneous sympathetic and parasympathetic activity, such as may occur with bowel or bladder distension pain or a pressure ulcer. It is usually a medical emergency requiring care in an intensive care unit. A cerebrovascular accident and death may occur during an attack.

Functional electrical stimulation (FES) is the direct application of electric current to intact nerve fibers in a coordinated fashion to cause involuntary but purposeful muscle contraction. FES bypasses the central nervous system and targets motor neurons innervating either skeletal muscle or other organ systems. When used for rehabilitation of patients with spinal cord injury, FES is used to improve general health and fitness through exercise and to enable functional use of partially or completely paralyzed limbs (Hayes).

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Related Policies, Processes and Other Documents
N/A

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

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10/1/2026	Health Care Services	Revised
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