Electrical Stimulation Devices for Home Use

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Developed By: Medical Necessity Criteria Committee

I. Description

Electrical stimulators are small electronic devices that are worn externally by a patient and affixed to the skin by way of electrodes. Electrical stimulators may be used for a variety of purposes including reducing acute post-operative pain and swelling, treating chronic intractable pain, maintaining muscle tone during temporary extremity immobilization, reducing spasticity, and assisting spinal cord injured patients to grasp, stand, and walk independently. Electrical stimulators for use by patients in the home setting can be further broken down into the following categories:

Transcutaneous Electrical Nerve Stimulation (TENS): Electrical impulses are sent from a portable, battery-powered pulse generator using skin electrodes placed over the affected tissue. TENS is characterized by biphasic current and selectable parameters. It stimulates sensory nerves to block pain signals and generate endorphins. TENS is commonly used for the treatment of acute post-operative pain and chronic intractable pain.

Neuromuscular Electrical Stimulation (NMES): Also known as therapeutic electrical stimulation, NMES strengthens muscles weakened by disuse. Through multiple channels, NMES attempts to stimulate motor nerves and alternately causes contraction and relaxation of muscles. These devices are used to prevent or stop disuse atrophy, relax muscle spasm, increase blood circulation, maintain or increase range-of-motion, and re-educate muscles.

Functional Neuromuscular Stimulation (FNS or ENS-Electrical Neuromuscular Stimulation): FNS attempts to replace destroyed nerve pathways through electrical stimulation of muscles. This is performed in an attempt to enable spinal cord injured patients to grasp, stand or walk independently or at least maintain healthy muscle tone and strength.

H-wave Stimulation: H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation in terms of its waveform. H-wave stimulation is intended to emulate the H waveform found in nerve signals and therefore enables greater and deeper penetration of a low frequency current while using less power than other machines. H-wave stimulation must be distinguished from the H-waves that are a component of electromyography.
Interferential Stimulation: Interferential stimulation is a type of electrical stimulation that uses paired electrodes of two independent circuits carrying medium-frequency alternating currents. Interferential

stimulators have been investigated as a technique to reduce pain, restore muscle function and improve range of motion. An example of an interferential stimulation device is the RS-4i.

Microcurrent Stimulation (MENS): Microcurrent stimulation machines have been used for the symptomatic relief of chronic intractable pain and as an adjunctive treatment in the management of post-surgical pain problems. MENS utilizes a unique waveform that acts on the body's naturally occurring electrical impulses to decrease pain and facilitate healing. MENS units have also been used in the treatment of migraines, anxiety, depression, insomnia, and cognitive dysfunction. An example of a MENS device is the Alpha-Stim.

Galvanic Stimulation: Galvanic stimulation applies high voltage, direct current to reduce edema in acute injuries associated with major tissue trauma. Direct current creates an electrical field over the treated area that, theoretically, changes blood flow. The positive pad behaves like ice, causing reduced circulation to the area and a reduction in swelling. The negative pad behaves like heat, causing increased circulation and faster healing. An example of a galvanic stimulator is the SporTS.

Sympathetic Therapy: Sympathetic therapy is used for the symptomatic relief of chronic pain. Electrical stimulation is delivered via peripheral nerves in order to create a form of stimulation of the sympathetic nervous system. Sympathetic therapy is initiated in a clinical setting followed by home therapy:

BioniCare® Knee Device: BioniCare® utilizes low-level pulsed electrical stimulation for relieving pain and symptoms associated with osteoarthritis of the knee.

Peripheral Subcutaneous Field Stimulation: Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS) consists of implantation of a stimulation device in the subcutaneous tissue over a painful area. It is used when the specific peripheral nerve generators cannot be defined. The clinical effectiveness of PSFS or PNFS remains unproven and further clinical studies are needed.

Peroneal Nerve Stimulation: The WalkAide attaches to the leg, just below the knee, and stimulates the common peroneal nerve during the gait cycle. It is intended to counteract foot drop by producing dorsiflexion during the swing phase of the gait. Other similar devices include the NESS L300, and ODFS Dropped Foot Stimulator. There is insufficient evidence in the peer reviewed literature that use of these devices will improve function in patients with gait disorders.

Auricular Stimulation (P-stim): Auricular stimulation involves the stimulation of acupuncture points on the ear. Devices, including the P-stim and E-pulse, have been developed to provide ambulatory auricular electrical stimulation over a period of several days. The devices are being evaluated for a variety of conditions including pain, depression, anxiety, and weight loss. The literature is limited in quantity and the available trials are not of high quality. Additional larger, randomized, controlled studies are needed to evaluate the efficacy of this treatment.

II. Criteria: CWQI HCS-0027

A. Moda Health considers **electrical stimulators for home use** medically necessary for **1 or more** of the following criteria:

a. **Moda Health will allow coverage for Neuromuscular electrostimulation (NMES) up to the plan limitations for the prevention and/or treatment of disuse muscle atrophy** when **ALL** of the following criteria are met:

i. Device must be FDA approved.
ii. The nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves
iii. The patient had previous casting or splinting of a limb, contractures due to burn scarring, prolonged immobilization due to injury, or major hip or knee surgery *(until physical therapy begins)*
iv. The patient was unresponsive to conservative treatment such as physical therapy, pharmacotherapy, etc.
v. The patient is at least 2 years of age
vi. If the above criteria are met, approval for NMES will be limited to a 2-month rental. Further authorization will require review of the patient's current condition and response to NMES.
vii. Moda Health consider NMES experimental and investigational for **ALL** of the following uses:
    1. General muscle strengthening in healthy individuals
    2. Treatment of scoliosis
    3. Treatment of denervated muscles
    4. Cardiac conditioning
    5. Facilitating voluntary motor control
viii. The request for CyMedica QB1 System (form fitted conductive knee brace) is **NOT** covered as this NMES unit is considered experimental and Investigational.

b. **Moda Health considers form-fitting conductive garments medically necessary for use with an approved NMES** when **All** of the following conditions are met:

i. The conductive garment is approved for marketing by the FDA
ii. A physician has prescribed the conductive garment for use in delivering covered NMES
iii. The patient cannot manage without the conductive garment due to **1 or more** of the following conditions:
    1. The area is too large or there are too many sites to be stimulated using conventional electrodes, adhesive tape, and lead wires
    2. Frequent stimulation is required that would preclude use of conventional electrodes, adhesive tapes, and lead wires
    3. The patient has chronic intractable pain that is inaccessible with the use of conventional electrodes, adhesive tapes, and lead wires.

4. The patient has skin problems that preclude the application of electrodes, adhesive tapes and lead wires.
5. The patient requires electrical stimulation beneath a cast to treat chronic intractable pain

iv. Requests for non-FDA approved devices are considered experimental and investigational as high-quality peer-reviewed medical literature does not support the efficacy of the device for patient treatment (e.g. CyMedica QB1 device)

c. **Moda Health will allow coverage for FES *(e.g. Parastep I System)* to plan limitations when used to assist members with spinal cord injuries to ambulate** when **All** of the following criteria are met:
   i. Intact L1 and below motor units
   ii. Six months post spinal cord injury and restorative surgery
   iii. Ability to weight bear with both upper and lower extremities
   iv. Ability to independently maintain upright posture
   v. Ability to transfer and maintain standing position for at least three minutes
   vi. Presence of hand and finger function to operate controls
   vii. Positive brisk muscle contraction response to neuromuscular electrical stimulation
   viii. Sensory perception of electrical stimulation is sufficient for muscle contraction
   ix. Absence of hip/knees degenerative disease and long bone fracture secondary to osteoporosis
   x. Patient is highly motivated and has the cognitive ability to operate device
   xi. Patient has successfully completed a training program which includes at least 32 physical therapy sessions using the device over a three-month period
   xii. The patient does **NOT** have any of the following contraindications:
      1. Cardiac pacemaker
      2. Severe scoliosis (greater than 40 degrees) or severe osteoporosis (T score of less than -2.5 SD with fragility fractures)
      3. Skin disease or cancer at the area of stimulation
      4. Irreversible contracture(s)
      5. Autonomic dysreflexia

d. **Peripherally implanted nerve stimulation** *(also known as Percutaneous Electrical Nerve Stimulation **(PENS)*** is medically necessary for patients with 1 **or more** of the following conditions:
   i. Treatment of patients with **chronic intractable low back pain secondary to degenerative disc disease**, refractory to other conservative treatment *(i.e. analgesics, physical therapy, steroid injections, surgery) and **ALL** of the following:*
      1. The patient is part of a multi-modality rehabilitation program (i.e. exercise)

   ii. Treatment of patients with **intractable neurogenic pain** when **ALL** of the following criteria are met:
      1. Patient has chronic intractable pain, refractory to other methods of treatment *(i.e. analgesics, physical therapy, local injection, surgery, etc.)*
      2. Patient has undergone a psychological evaluation and been approved as appropriate for peripheral stimulation.

3. Trial of transcutaneous stimulation was successful (resulting in at least 50% reduction in pain)
4. Patient does not have an addiction to opioids
5. There is objective evidence of pathology *(i.e. EMG, MRI)*

iii. The treatment of patients with **diabetic neuropathy or neuropathic pain** that meets **ALL** of the following criteria:
1. The patient has failed adequate response to conventional treatments including **2 or more** of the following groups of agents:
a. Anti-convulsants *(e.g. pregabalin)*
b. Anti-depressants (*e.g. amitriptyline, duloxetine)*
c. Other pharmacological agents *(e.g. Capsaicin, isosorbide dinitrate spray)*

e. Moda Health considers **functional neuromuscular stimulations (FNS)** experimental and investigational for all indications including but not limited to assisting spinal cord injured patients to stand, grasp and walk independently.

f. Moda Health considers **ALL** of the following electrical stimulation devices experimental and investigational for any indication because their effectiveness has not been established:
i. Interferential stimulators (see separate criteria for interferential stimulation devices)
ii. H-wave stimulators
iii. Microcurrent stimulators (e.g. Alpha-Stim)
iv. Galvanic stimulators (e.g. SportTX)
v. Sympathetic stimulators
vi. BioniCare® Knee Device
vii. Peripheral subcutaneous field stimulation
viii. Peroneal nerve stimulation (such as Walkaide, Ness L300, ODFS Dropped Foot Stimulator), for gait disorders (e.g. foot drop) due to CNS disorders including but not limited to multiple sclerosis and stroke.

g. **Auricular stimulation (e.g. P-stim or E-pulse)** is considered experimental and investigational for ALL of the following indications including but not limited to:
i. Chronic pain
ii. Migraines
iii. Post-operative spinal surgery pain control
iv. Depression
v. Anxiety
vi. Weight loss
vii. Insomnia

h. TENS is considered Experimental and Investigational for **ALL** of the following diagnosis and devices;
i. Diagnosis (F01.50-F99; G47.00-G47.9)

1. F01.50-F99 Mental disorders (Anxiety, Depression, PTSD)
2. G47.00-G47.9 Sleep Disorders (Insomnia, Mood and Sleep disturbances)

ii. Cranial Electrical Stimulation Devices
1. Fisher Wallace
2. CES Ultra

III. Information Submitted with the Prior Authorization Request:

1. Ordering physician's chart notes
2. Appropriate imaging studies or other diagnostic test results
3. Conservative treatment trialed

IV. CPT or HCPC codes covered:

Codes	Description
A4595	ELECTRICAL STIMULATOR SUPPLIES, 2 LEAD, PER MONTH, (E.G., TENS, NMES)
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0764	Functional neuromuscular stimulator, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0770	Function electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
64555	Peripheral nerve (excludes sacral nerve)
64561	Sacral nerve (transforaminal placement), including image guidance, if performed
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

V. CPT or HCPC codes NOT covered:

Codes	Description
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-to-one contact with the patient (P-Stim device)

VI. Annual Review History

Review Date	Revisions	Effective Date
11/2012	Annual Review: Added table with review date, revisions, and effective date. Added conservative therapy to NMES 2.c. Formatting corrected 4.j instead of 5.	12/01/2012

09/2013	Annual Review: No changes	09/25/2013
08/2014	Annual Review: Added peripherally implanted stimulators	08/30/2014
09/2015	Annual Review- Added CMS guidelines, ICD-10 codes, changed name to Electrical Stimulation Devices, added auricular stimulation device criteria and codes.	10/28/2105
11/2016	Annual review, updated CMS guidelines, ICD-10 codes, added diabetic neuropathy criteria	11/30/2016
10/2017	Annual review-Transferred to new template	10/25/2017
10/2018	Annual Review- No Changes	10/2018
10/2019	Annual Review – removed deleted codes	11/01/2019
05/2020	Annual Review – Removed indications for TENS as this procedure is currently not medically reviewed. Added missing criteria indications that are considered experimental and investigational (f, g, h)	06/01/2020
05/2021	Annual Review: Added TENS Dx and devices that are considered E/I	06/01/2021
04/2022	Annual Review: Minor grammar updates	05/01/2022
04/2023	Annual Review: No changes	05/01/2023

VII. References

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32. Centers for Medicare & Medicaid Services Local Coverage Article: Transcutaneous Electrical Nerve Stimulators (TENS)-Policy Article- Effective October 2015 (A52520); Noridian Healthcare Solutions, LLC: Original Article Effective Date 10/01/2015; Revision Effective Date 07/01/2016.
33. Physician Advisors

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description
G56.00-G59	Mononeuropathies
G89.18	Other acute postprocedural pain
G89.21-G89.29	Chronic pain
G89.4	Chronic pain syndrome
G90.50-G90.59	Complex regional pain syndrome I (CRPS I)
M51.04-M51.06	Thoracic, thoracolumbar and lumbosacral intervertebral disc disorders with myelopathy
M51.24-M51.37	Other thoracic, thoracolumbar and lumbosacral intervertebral disc displacement and degeneration
M54.10 - M54.18	Radiculopathy
M54.30 - M54.32	Sciatica
M54.40 - M54.42	Lumbago with sciatica
M54.5	Low back pain [lumbago]
M54.6	back pain [lumbago] M54.6 Pain in thoracic spine
M62.40-M62.49	Contracture of muscle
M62.50-M62.59	Muscle wasting and atrophy, not elsewhere classified
M63.80- M63.89	Disorders in muscles not classified elsewhere
M79.2	Neuralgia and neuritis, unspecified [neuropathic pain]
M70.031-M79.9	Other soft tissue disorder
M96.1	Postlaminectomy syndrome, lumbar region
R52	Pain, unspecified
S12.ØØØA-S - S14.109A-S	Fracture of cervical vertebra and other parts of neck (A - initial encounter for closed fracture; B - initial encounter for open fracture; D – subsequent encounter for fracture with routine healing; G - subsequent encounter for fracture with delayed healing; K - subsequent encounter for fracture with nonunion; S –
S22.010A-S – S24.159A-S	Fracture of thoracic vertebra (A - initial encounter for closed fracture; B - initial encounter for open fracture; D – subsequent encounter for fracture with routine healing; G - subsequent encounter for fracture with delayed healing; K - subsequent encounter for fracture with nonunion; S – sequela
S32.009A-S – S32.059A-S	Fracture of lumbar vertebra initial encounter (A - initial encounter for closed fracture; B - initial encounter for open fracture; D – subsequent encounter for

	fracture with routine healing; G - subsequent encounter for fracture with delayed healing; K - subsequent encounter for fracture with nonunion; S – sequela)
S34.101A-S – S34.139A-S	Injury of lumbar and sacral spinal cord and nerves at abdomen, lower back (lumbar and sacral spinal cord and pelvis level (A – initial encounter; D – subsequent encounter; S - sequela)
S44.8x1 - S44.92xS	Injury of other nerves at shoulder and upper arm level
S64.8x1 - S64.92xS	Injury of other nerves at wrist and hand level
S74.8x1 - S74.92xS	Injury of other nerves at hip and thigh level
S84.801 -S84.92xS	Injury of other nerves at lower leg level
S94.8x1- S94.92xS	Injury of other nerves at ankle and foot level
T23.001A-S – T23.779A-S	Burn and corrosion of wrist and hand (A – initial encounter; D – subsequent encounter; S - sequela)
T24.001A-S – T24.799A	Burn and corrosion of lower limb, except ankle and foot (A – initial encounter; D – subsequent encounter; S - sequela)
T25.011A-S – T25.799A-S	Burn or corrosion of ankle and foot (A – initial encounter; D – subsequent encounter; S - sequela)
T30.0-T32.99	Burns and corrosions of multiple and unspecified body regions

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	**NCD/LCD Document (s):**
N/A	

NCD/LCD Document (s):
NCD: 280.13 Transcutaneous Electrical Nerve Stimulators (TENS)
NCD: 160.7 Electrical Nerve Stimulators
LCD: L33802 Transcutaneous Electrical Nerve Stimulators (TENS)
LCA: A52520 Transcutaneous Electrical Nerve Stimulators (TENS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC