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Corporate Medical Policy

Neurostimulation, Electrical

File Name:	neurostimulation_electrical
Origination:	4/2004
Last Review:	4/2023

Neuromuscular electrical stimulators are divided into two broad categories: therapeutic and functional. Therapeutic electrical stimulation strengthens muscles weakened by disuse while functional electrical stimulation attempts to replace destroyed nerve pathways by electrical stimulation to the muscle in order to assist a functional movement. Procedures or services described in this policy include the following:

- Section I Functional Neuromuscular Electrical Stimulation
- Section II Peripheral Subcutaneous Field Stimulation
- Section III Neuromuscular Electrical Stimulation (NMES)
- Section IV Threshold Electrical Stimulation

Various electrical stimulation devices are marketed to relieve a wide range of conditions including, but not limited to, muscle or joint pain, stress, insomnia, depression, back pain, migraines, and disuse atrophy. These devices employ forms of electrical stimulation such as monophasic pulsed electric field therapy, microcurrent therapy or other forms of electrotherapy.

Related Policies:

Interferential Stimulation TENS (Transcutaneous Electrical Nerve Stimulation) Spinal Cord and Dorsal Root Ganglion Stimulation Electrical Stimulation for the Treatment of Arthritis Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS) Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction Vagus Nerve Stimulation Occipital Nerve Stimulation Electrostimulation and Electromagnetic Therapy for Wounds Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence Electrical Bone Growth Stimulation Gastric Electrical Stimulation

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Functional Neuromuscular Electrical Stimulation, Peripheral Subcutaneous Field Stimulation, Neuromuscular Electrical Stimulation, and Threshold Electrical Stimulation are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

NOTE: Other Electrical Stimulation Devices:

BCBSNC does not cover ANY of the following electrical stimulation devices, because each is considered experimental, investigational, or unproven for the treatment of any condition (this list may not be all inclusive):

- bioelectric nerve block (electroceutical therapy) (HCPCS Code E1399)
- cranial electrical stimulation (cranial electrotherapy stimulation) (Code 64553; HCPCS Code E1399)
- electrical sympathetic stimulation therapy (HCPCS Code E1399)
- electro therapeutic point stimulation (ETPSSM) (HCPCS Code E1399)
- functional electrical stimulation (FES) (HCPCS Codes E0764, E0770)
- H-WAVE electrical stimulation (HCPCS Code E1399)
- high-voltage galvanic stimulator (HVG) (HCPCS Code E1399)
- interferential therapy (IFT) (HCPCS Codes S8130, S8131)
- microcurrent electrical nerve stimulation (MENS), including frequency-specific microcurrent (FSM) stimulation (HCPCS Code E1399)
- multiple modality (interferential current, neuromuscular electrical, and transcutaneous electrical nerve) stimulation (NexWave, Zynex) (multiple codes)
- pelvic floor electrical stimulation (PFES) (HCPCS Code E0740)
- percutaneous electrical nerve stimulation (PENS) (Code 64999; HCPCS Code E1399) *Providers may* submit claims for these services using the unlisted code 64999. Providers should not be using 64553-64565, or 64590 to bill this service as these codes are not appropriate.
- percutaneous neuromodulation therapy (PNT) (HCPCS Code E1399)
- threshold/therapeutic electrical stimulation (TES) (HCPCS Code E1399)
- transcutaneous electrical acupoint stimulation (TEAS) (HCPCS Code E0765)
- transcutaneous electrical joint stimulation (HCPCS Code E0762)
- auricular electroacupuncture (HCPCS Code S8930)
- transcutaneous electrical modulation pain reprocessing (TEMPR) (Scrambler therapy, Calmare®) (Code 0278T)

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

I. Functional Neuromuscular Electrical Stimulation

Functional electrical stimulation (FES) involves the use of an orthotic device or exercise equipment with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function and improve health in patients with damaged or destroyed nerve pathways (eg, spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy).

One application of functional electrical stimulation is to restore upper extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadriplegia). The Neurocontrol Freehand[®] system is an implantable upper extremity neuroprosthesis intended to improve a patient's ability to grasp, hold, and release objects, and is indicated for use in patients who are tetraplegic due to C5 or C6 spinal cord injury. NeuroControl Corp. is no longer in business, but NMES centers in the United States and United Kingdom provide maintenance for implanted devices. The NESS H200[®] (previously known as the Handmaster NMS I) is another device that uses surface electrodes and is purported to provide hand active range of motion and function for patients with stroke or C5 tetraplegia.

Other FES devices have been developed to provide FES for patients with foot drop. Foot drop is weakness of the foot and ankle that causes reduced dorsiflexion and difficulty with ambulation. It can have various causes such as cerebral palsy, stroke or multiple sclerosis. Functional electrical stimulation of the peroneal nerve has been suggested for these patients as an aid in raising the toes

during the swing phase of ambulation. In these devices, a pressure sensor detects heel off and initial contact during walking. A signal is then sent to the stimulation cuff, initiating or pausing the stimulation of the peroneal nerve, which activates the foot dorsiflexors. Examples of such devices used for treatment of foot drop are the Innovative Neurotronics' (formerly NeuroMotion, Inc.) WalkAide®, Bioness' L300 GoTM, MyGait (Otto Bock HealthCare), and the Odstock Dropped Foot Stimulator. An implantable peroneal nerve stimulator system (ActiGait) is being developed in Europe.

Another application of functional electrical stimulation is to provide spinal cord injured patients with the ability to stand and walk. Generally, only spinal cord injury patients with lesions from T4 to T12 are considered candidates for ambulation systems. Lesions at T1–T3 are associated with poor trunk stability, while lumbar lesions imply lower extremity nerve damage. Using percutaneous stimulation, the device delivers trains of electrical pulses to trigger action potentials at selected nerves at the quadriceps (for knee extension), the common peroneal nerve (for hip flexion), and the paraspinals and gluteals (for trunk stability). Patients use a walker or elbow-support crutches for further support. The electrical impulses are controlled by a computer microchip attached to the patient's belt that synchronizes and distributes the signals. In addition, there is a finger-controlled switch that permits patient activation of the stepping.

Other devices include a reciprocating gait orthosis (RGO) with electrical stimulation. The orthosis used is a cumbersome hip-knee-ankle-foot device linked together with a cable at the hip joint. The use of this device may be limited by the difficulties in putting the device on and taking it off.

Neuromuscular stimulation is also proposed for motor restoration in hemiplegia and spinal cord injury and treatment of secondary dysfunction (e.g., muscle atrophy and alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways. There are commercially available exercycles that use electrical muscle stimulation technology as a means of physical therapy and exercise for spinal cord injury patients. It is thought that these devices may be used to promote cardiovascular conditioning, prevent muscle atrophy, and/or maintain bone mass. The patient's legs are wrapped in fabric strips that contain electrodes to stimulate the muscles, thus permitting the patient to pedal. These exercycles are sometimes called functional neuromuscular exercisers.

Regulatory Status

The Neurocontrol Freehand[®] system received approval from the U.S. Food and Drug Administration (FDA) in 1997 through the pre-market approval (PMA) process. The implantable Freehand [®] System is no longer marketed in the United States. The Handmaster NMS I system (now named NESS H200[®]) was originally cleared for use in maintaining or improving range of motion, reducing muscle spasm, preventing or retarding muscle atrophy, providing muscle re-education, and improving circulation; in 2001, its 510(k) marketing clearance was expanded to include provision of hand active range of motion and function for patients with C5 tetraplegia.

The WalkAide device first received 510(k) marketing clearance from the FDA in the 1990s; the current version of the WalkAide device received 510(k) marketing clearance in September 2005. The Odstock Dropped Foot Stimulator received 510(k) marketing clearance in 2005. The Bioness L300 Go[®] received 510(k) marketing clearance in 2019. The MyGait® Stimulation System (Otto Bock HealthCare) received 510(k) marketing clearance in 2015. The FDA summaries for the devices state that they are intended to be used in patients with drop foot by assisting with ankle dorsiflexion during the swing phase of gait.

To date, the Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the FDA. The Parastep device is approved to "enable appropriately selected skeletally mature spinal cord injured patients (level C6-T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury."

The ERGYS (Therapeutic Alliances), The RT300 (Restorative Therapies, Inc) and Myocycle Home (Myolyn) are cycle ergometers that have been cleared by FDA.

Related policies:

Microprocessor Controlled Prostheses for the Lower Limb Myoelectric Prosthetic Components for the Upper Limb Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

When Functional Neuromuscular Electrical Stimulation is covered

Not applicable.

When Functional Neuromuscular Electrical Stimulation is not covered

Neuromuscular stimulation is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations:

- As a technique to provide ambulation in patients with spinal cord injury; or
- To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke); or
- To improve ambulation in patients with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., post-stroke or in those with multiple sclerosis).

Functional electrical stimulation devices for exercise in patients with spinal cord injury is considered investigational.

*****Note:** Physical fitness equipment (with or without functional neuromuscular electrical stimulation capability) is excluded under most member benefit plans. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Policy Guidelines

For individuals who have loss of hand and upper-extremity function due to spinal cord injury or stroke who receive FES, the evidence includes a few small case series. Relevant outcomes are functional outcomes and quality of life. Interpretation of the evidence is limited by the low number of patients studied and lack of data demonstrating the utility of FES outside the investigational setting. It is uncertain whether FES can restore some upper-extremity function or improve quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic footdrop who receive FES, the evidence includes randomized controlled trials (RCTs), a systematic review and meta-analyses, and a longitudinal cohort study. Relevant outcomes are functional outcomes and quality of life. For chronic poststroke footdrop, two RCTs comparing FES with a standard ankle-foot orthosis showed improved patient satisfaction with FES but no significant differences between groups in objective measures like walking. Another RCT found no significant differences between use versus no use of FES on walking outcomes. Similarly, one meta-analysis found no difference between AFO and FES in walking speed, and another meta-analysis found no difference between FES and conventional treatments. The cohort study assessed patients' ability to avoid obstacles while walking on a treadmill using FES versus AFO. Although the FES group averaged a 4.7% higher rate of avoidance, the individual results between devices ranged widely. One RCT with 53 subjects examining neuromuscular stimulation for footdrop in patients with multiple sclerosis showed a reduction in falls and improvement in patient satisfaction compared with an exercise program, but did not demonstrate a clinically significant benefit in walking speed. Another RCT showed that at 12 months, both FES and AFO had improved walking speed, but the difference in improvement between the two

devices was not significant. Another study found FES (combined with postural correction) and neuroproprioceptive facilitation and inhibition physiotherapy did not differ in in walking speed or balance immediately or 2 months after program end. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be corroborated. The literature on FES in children with cerebral palsy includes a systematic review of small studies with within-subject designs. Further study is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spinal cord injury at segments T4 to T12 who receive FES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. No controlled trials were identified on FES for standing and walking in patients with spinal cord injury. However, case series are considered adequate for this condition, because there is no chance for unaided ambulation in this population with spinal cord injury at this level. Some studies have reported improvements in intermediate outcomes, but improvement in health outcomes (e.g., ability to perform activities of daily living, quality of life) have not been demonstrated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spinal cord injury who receive FES exercise equipment, the evidence includes prospective within-subject comparisons. The relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on FES exercise equipment consists primarily of within-subject, pre- to posttreatment comparisons. Evidence was identified on two commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is a limited amount of evidence on the RT300 series. None of the studies showed an improvement in health benefits and one analysis of use for 314 individuals over 20000 activity sessions with a Restorative Therapies device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of six days per week, but caloric expenditure remained low. Compliance was shown in one study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function. A limitation of these studies is that they all appear to have been conducted in supervised research centers. No studies were identified on longterm home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing and Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable code(s): 64580, E0764, E0770.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

II. Peripheral Subcutaneous Field Stimulation

Peripheral subcutaneous field stimulation (PSFS, also called peripheral nerve field stimulation or target field stimulation) is a form of neuromodulation that is intended to treat chronic neuropathic pain. One application of PSFS that is being evaluated is occipital or craniofacial stimulation for headache/migraines, craniofacial pain, or occipital neuralgia. PSFS is also being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and post-herpetic neuralgia.

PSFS is a modification of peripheral nerve stimulation. In PSFS, leads are placed subcutaneously within the area of maximal pain. The objective of PSFS is to stimulate the region of affected nerves, cutaneous afferents, or the dermatomal distribution of the nerves, which then converge back on the spinal cord. Combined spinal cord stimulation and PSFS is also being evaluated.

Similar to spinal cord stimulation or peripheral nerve stimulation, permanent implantation is preceded by a percutaneous stimulation trial with at least 50% pain reduction. Currently, there is no consensus regarding the indications for PSFS. Criteria for a PSFS trial may include a clearly defined, discrete focal area of pain with a neuropathic or combined somatic/neuropathic pain component with characteristics of burning and increased sensitivity, and failure to respond to other conservative treatments including medications, psychological therapies, physical therapies, surgery, and pain management programs.

The mechanism of action in PSFS is not known. Theories include an increase in endogenous endorphins and other opiate-like substances; modulation of smaller A-delta and C nerve fibers with stimulation of large-diameter A-beta fibers; local stimulation of nerve endings in the skin; local anti-inflammatory and membrane depolarizing effect; or a central action via antegrade activation of A-beta nerve fibers. Complications of PSFS include lead migration or breakage and infection of the lead or neurostimulator.

Regulatory Status

In July 2018, the SPRINT[®] Peripheral Nerve Stimulation System (SPR Therapeutics, Inc) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K181422). FDA determined that this device was substantially equivalent to existing devices for use in pain management. PSFS is also an off-label use of spinal cord stimulation devices that have been approved by the Food and Drug Administration for the treatment of chronic pain.

Related policies:

Spinal Cord and Dorsal Root Ganglion Stimulation TENS(Transcutaneous Electrical Nerve Stimulation) Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS) Occipital Nerve Stimulation

When Peripheral Subcutaneous Field Stimulation is covered

Not applicable.

When Peripheral Subcutaneous Field Stimulation is not covered

Peripheral subcutaneous field stimulation is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Policy Guidelines

For individuals who have chronic neuropathic pain who receive PSFS, the evidence includes one randomized controlled trial (RCT), one nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT, which used a crossover design, did not compare PSFS to alternatives. Rather, this study compared different methods of PSFS. Among study participants, 24 (80%) of 30 patients had at least 50% reduction in pain with any type of PSFS. However, because the RCT did

not include a sham group or comparator with a different active intervention, this study offers little evidence for efficacy beyond that of a prospective, uncontrolled study. In addition, case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Prospective controlled trials comparing PSFS with placebo or alternative treatment modalities are needed to determine the efficacy of this treatment for chronic pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 64596, 64597, 64598, 64999, 0720T, C1767

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

III. Neuromuscular Electrical Stimulation (NMES)

Neuromuscular electrical stimulation is used primarily in the orthopedic setting as treatment before and after orthopedic procedures to strengthen or rehabilitate muscles as well as in the physical medicine and rehabilitation/neurology settings. The major use of NMES is for prevention and retardation of disuse atrophy in conditions that causes immobilization of a joint or extremity in postsurgical joint procedures/arthroplasties as well as other musculoskeletal and neurologic conditions/injuries.

This device uses electrodes placed on the skin to stimulate motor nerves to alternately contract and relax the muscle. This treatment requires that an intact nerve is available to the muscle that is being rehabilitated.

When Neuromuscular Electrical Stimulation (NMES) is covered

Not applicable.

When Neuromuscular Electrical Stimulation (NMES) is not covered

All indications for neuromuscular electrical stimulation (NMES) including disuse atrophy are not covered. Neuromuscular electrical stimulation is considered investigational. BCBSNC does not cover investigational services or supplies.

NOTE: Form-fitting conductive garments used with NMES are considered a convenience item and are not covered.

NOTE: Devices that provide multiple modality functions including but not limited to interferential, NMES and TENS (Transcutaneous Electrical Nerve) stimulation are not covered and are considered investigational. BCBSNC does not cover investigational services or supplies.

Policy Guidelines

Study results in peer-reviewed literature are insufficient to prove that NMES for disuse atrophy is effective.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: A4556, A4557, A4595, E1399, E0720, E0730, E0731, E0740, E0744, E0745, E0762, E0769, E0770, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

IV. Threshold Electrical Stimulation

Threshold electrical stimulation is provided by a small electrical generator, lead wires, and surface electrodes that are placed over the target muscles. The intensity of the stimulation is set at the sensory threshold and does not cause a muscle contraction.

Threshold electrical stimulation is described as the delivery of low intensity electrical stimulation to target spastic muscles during sleep at home. The stimulation is not intended to cause muscle contraction. Although the mechanism of action is not understood, it is thought that low intensity stimulation may increase muscle strength and joint mobility, leading to improved voluntary motor function. The technique has been used most extensively in children with spastic diplegia related to cerebral palsy (CP), but also in those with other motor disorders, such as spina bifida.

Devices used for threshold electrical stimulation are classified as "powered muscle stimulators." As a class, the U.S. Food and Drug Administration (FDA) describes these devices as "an electronically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area."

When Threshold Electrical Stimulation is covered

Not applicable.

When Threshold Electrical Stimulation is not covered

All indications for threshold electrical stimulation for orthopedic/musculoskeletal/neurological conditions are not covered and are considered investigational. BCBSNC does not cover investigational services or supplies.

Policy Guidelines

The studies published to date demonstrate that threshold electrical stimulation is not effective for treatment of spasticity, muscle weakness, reduced joint mobility, or motor function.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: A4595, E0731, E0745

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Policy entitled: Therapeutic Electrical Stimulation (TES)

Plan Consultant - 12/96

Physician Advisory Group Review 2/97

Medical Policy Advisory Group Review 3/99

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual, 1.01.19; 10/08/02

ECRI Hotline Response: Neuromuscular Electrical Stimulation for Cerebral Palsy and Spina Bifida. (Updated June 11, 2002); accessed 7/18/03 at www.ecri.org

ECRI Hotline Response: Neuromuscular Electrical Stimulation for Disuse Atrophy. (Updated on 9/3/02); accessed 7/18/03 at www.ecri.org

United Cerebral Palsy website regarding "Therapeutic Electrical Stimulation" and "The Use of Electrical Stimulation of Spastic Muscles" accessed 7/18/2003 at www.ucp.org

Policy entitled: Functional Neuromuscular Stimulation (FNS)

BCBSA Medical Policy Reference Manual - 3/96

MEDLINE search January 1996 through July 1997

MEDLINE search July 1997 through August 1999

Medical Policy Advisory Group 12/2/1999

BCBSA Medical Policy Reference Manual, 8.03.01; 4/30/2000

Specialty Matched Consultant Advisory Panel, 8/2001

BCBSA Medical Policy Reference Manual, 8.03.01; 12/18/02

Specialty Matched Consultant Advisory Panel - 7/2003

New Policy entitled: Electrical Stimulators, Neuromuscular

BCBSA Medical Policy Reference Manual [Electronic Version], 1.01.19, 2/25/2004.

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/25/2004.

Specialty Matched Consultant Advisory Panel - 6/2004

Fehlings, D.L., Kirsch, S., McComas, A., Chipman, M., Campbell, K. (2002, November) Evaluation of therapeutic electrical stimulation to improve muscle strength and function in children with types II/III spinal muscular atrophy. Developmental Medicine and Child, 44(11), 741-4. Retrieved 4/16/04 from http://212.49.218.200/newgenMB/asp/Document.asp?docNo=25919.

BCBSA Medical Policy Reference Manual [Electronic Version], 12/14/2005.

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 12/14/2005.

Specialty Matched Consultant Advisory Panel - 5/2006

BCBSA Medical Policy Reference Manual [Electronic Version], 1.01.19, 12/12/2006.

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 12/13/2007.

Specialty Matched Consultant Advisory Panel - 5/2008

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 10/6/2009

Senior Medical Director Review – 5/2010

BCBSA Medical Policy Reference Manual [Electronic Version], 1.01.19, 9/10/2009

Specialty Matched Consultant Advisory Panel – 11/2010

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/10/2011

BCBSA Medical Policy Reference Manual [Electronic Version], 1.01.19, 2/10/2011

Brosseau L, Wells GA, Finestone HM, et al. Clinical practice guidelines for electrical stimulation. 2006. Retrieved 5/9/2011 from <u>http://www.guideline.gov/content.aspx?id=9918</u>.

Monaghan B, Caulfield B, O'Mathúna DP. Surface neuromuscular electrical stimulation for quadriceps strengthening pre and post total knee replacement. Cochrane Database Syst Rev, 2010;(1):CD007177.

Medical Director – 6/2011

Specialty Matched Consultant Advisory Panel - 11/2011

Policy Name Change: Neurostimulation, Electrical

BCBSA Medical Policy Reference Manual [Electronic Version], 1.01.19, 11/10/2011

Medical Director - 1/2012

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/9/12

Specialty Matched Consultant Advisory Panel - 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version], 1.01.19, 11/8/2012

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/14/2013

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 3/14/2013

Specialty Matched Consultant Advisory Panel – 10/2013

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/13/2014

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 3/13/2014

Specialty Matched Consultant Advisory Panel - 10/2014

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/12/15

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 3/12/2015

Specialty Matched Consultant Advisory Panel - 10/2015

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 4/14/2016

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 8/11/2016

Specialty Matched Consultant Advisory Panel - 10/2016

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 4/13/2017

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 8/10/2017

Specialty Matched Consultant Advisory Panel – 10/2017

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 3/8/2018

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 4/12/2018

Specialty Matched Consultant Advisory Panel - 10/2018

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 4/8/2019

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 5/2/2019

Specialty Matched Consultant Advisory Panel - 10/2019

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 4/16/2020

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 5/21/2020

Specialty Matched Consultant Advisory Panel – 10/2020

BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 3/11/2021

BCBSA Medical Policy Reference Manual [Electronic Version], 7.01.139, 4/8/2021

Specialty Matched Consultant Advisory Panel - 10/2021

National Institute for Health and Care Excellence (NICE). Functional electrical stimulation for drop foot of central neurological origin [IPG278]. 2009; http://www.nice.org.uk/nicemedia/pdf/IPG278Guidance.pdf. Accessed January 24, 2021.

National Institute for Health and Care Excellence (NICE). Peripheral nerve-field stimulation for chronic low back pain [IPG451]. 2013; https://www.nice.org.uk/guidance/ipg451. Accessed February 9, 2021.

Specialty Matched Consultant Advisory Panel - 4/2022

Medical Director Review 4/2022

Specialty Matched Consultant Advisory Panel - 4/2023

Medical Director Review 4/2023

Policy Implementation/Update Information

Policy entitled: Therapeutic Electrical Stimulation (TES)

- 2/97 Original Policy issued: Physician Advisory Group Review
- 4/99 Reaffirmed based on Medical Policy Advisory Group
- 8/99 Reformatted, Medical Term Definitions added.
- 5/00 System coding change.
- 10/00 Specialty Matched Consultant Advisory Panel. No change recommended in criteria. System coding changes. Medical Policy Advisory Group review. No change in criteria. Approve.
- 2/02 Coding format change.
- 8/02 Specialty Matched Consultant Advisory Panel review 7/12/2002. No changes.

8/03 Description and Benefits Application sections revised. Key words added.

Policy entitled: Functional Neuromuscular Stimulation (FNS)

- 3/80 Original Policy: Experimental/Investigative
- 6/83 Reaffirmed
- 8/88 Reviewed: Investigational
- 9/99 Reformatted, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 3/01 System changes.
- 9/01 Specialty Matched Consultant Advisory Panel, 8/2001. Format changes.
- 7/03 Specialty Matched Consultant Advisory Panel, 7/15/03. No changes to criteria. Benefits Application section revised.
- 4/04 Billing/Coding section updated for consistency.

New Policy created entitled: Electrical Stimulators, Neuromuscular

- 7/29/04 Combined policies on Therapeutic Electrical Stimulation (TES) and Functional Neuromuscular Stimulation (FNS) and added section related to Neuromuscular Electrical Stimulation (NMES) for disuse atrophy. Therapeutic Electrical Stimulator (TES), Functional Neuromuscular Stimulation (FNS), and Neuromuscular Electrical Stimulation (NMES) for disuse atrophy are considered investigational. Specialty Matched Consultant Advisory Panel review 6/22/2004. References added. Notification given 7/29/2004. Effective date 10/14/2004.
- 1/5/06 Added 2006 HCPCS code E0764 to "Billing/Coding" section. Deleted HCPCS code E0752 from "Billing/Coding: section.
- 6/5/06 Specialty Matched Consultant Advisory Panel review 5/3/2006. No changes to policy intent. Removed "for disuse atrophy" from title in the "Neuromuscular Electrical Stimulation" section. Added statement to "When Neuromuscular Electrical Stimulation is Not Covered" to state; "All indications for neuromuscular stimulation (NMES) including disuse atrophy are not covered." Rationale added to "Policy Guidelines" for all sections. References added.
- 9/18/06 Added statement "Note: Form-fitting conductive garments used with NMES are considered a convenience item and are not covered." to the "When Not Covered" section.
- 1/17/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, and L8689 to the "Billing/Coding" section.
- 6/30/08 Specialty Matched Consultant Advisory Panel review 5/29/08. No change to policy statement. References added.
- 1/5/09 Added new HPCPS code E0770 to "Billing/Coding" section. (btw)

- 06/22/10 Policy number(s) removed. "Description" sections revised. "Therapeutic" removed from the name of Threshold Electrical Stimulation throughout policy as appropriate. Information added to the "Functional Neuromuscular Electrical Stimulation" section to indicate; Neuromuscular stimulation is considered investigational as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations: *As a technique to provide ambulation in patients with spinal cord injury; or *To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke); or *To improve ambulation in patients with foot drop caused by nerve damage (e.g., post-stroke or in those with multiple sclerosis)." No change to policy intent. Reviewed by Senior Medical Director 5/26/10. References added. (btw)
- 12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/2010. No changes to policy statements. Removed statement from the "Functional Neuromuscular Electrical Stimulation" "Description" section, "These applications are not addressed in this policy." References added. (btw)
- 6/21/11 Added HCPCS code, E0744 to "Billing/Coding" in the NMES section. "Description" section related to Threshold Electrical Stimulation revised. Removed reference to "Threshold Electrical Stimulation from the investigational policy statement. Added the following in the "Policy" section; "Threshold Electrical Stimulation is considered not medically necessary. BCBSNC does not provide coverage for services or procedures that are not medically necessary." Changed the statement in the "When Not Covered" section to indicate; "Threshold electrical stimulation as a treatment of motor disorders, including but not limited to cerebral palsy, is considered not medically necessary." "Policy Guidelines" revised. Reviewed with Medical Director 6/6/2011. References added. (btw)
- 7/19/11 Updated "Description" section under Functional Neuromuscular Electrical Stimulation. Added statement in the Functional Neuromuscular Electrical Stimulation's "When Not Covered" section to indicate *****Note:** Physical fitness equipment (with or without functional neuromuscular electrical stimulation capability) is excluded under most member benefit plans. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy." No change to policy intent. Medical Director review 7/1/2011. (btw)

Policy Name Change: Neurostimulation, Electrical

- 1/24/12 Policy name changed to Neurostimulation, Electrical. Specialty Matched Consultant Advisory Panel review 11/30/11. "Description" section updated under the "Functional Neuromuscular Electrical Stimulation" part of the policy. Section IV added to policy to address Peripheral Subcutaneous Field Stimulation. "Peripheral subcutaneous field stimulation is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures." New 2012 CPT codes added to "Billing/Coding" section: 0282T, 0283T, 0284T, 0285T. Reference added. (btw)
- 5/1/12 Reference added. (btw)
- 11/13/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. Policy Guidelines updated under the Functional Neuromuscular Electrical Stimulation section. No change to policy intent. (btw)
- 1/15/13 Reference added. (btw)

- 4/16/13 Description section updated and reformatted. Added "congenital disorders (e.g., cerebral palsy) or" to the third bullet under the When Not Covered section. Updated the Policy Guidelines. Reference added. Senior Medical Director review 4/1/2013. (btw)
- 5/28/13 Updated the Description and Policy Guidelines in the Peripheral Subcutaneous Field Stimulation section. No change to policy intent, Reference added. Senior Medical Director review 5/18/2013. (btw)
- 11/12/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. No change to policy. (btw)
- 12/31/13 Archived Neuromuscular Electrical Stimulation (NMES) and Threshold Electrical Stimulation sections of policy. (btw)
- 4/15/14 Description and Policy Guidelines updated in the Functional Neuromuscular Electrical Stimulation section. No change to policy intent. Reference added. (btw)
- 5/13/14 Policy Guidelines updated. Reference added. (btw)
- 12/9/14 Specialty Matched Consultant Advisory Panel review 10/28/2014. No change to Policy statement. (sk)
- 4/28/15 References added. (sk)
- 11/24/15 Specialty Matched Consultant Advisory Panel review 10/29/2015. (sk)
- 7/26/16 Reference added. Policy Guidelines updated. (sk)
- 11/22/16 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 10/26/2016. (sk)
- 12/30/16 Codes 0282T, 0283T, 0284T, and 0285T deleted from Billing/Coding section. Code 64999 added to Billing/Coding section. (sk)
- 11/10/17 References added. Specialty Matched Consultant Advisory Panel review 10/25/2017. (sk)
- 7/13/18 Reference added. (sk)
- 8/24/18 Reference added. (sk)
- 11/9/18 Specialty Matched Consultant Advisory Panel review 10/24/2018. (sk)
- 8/13/19 References added. Regulatory Status section updated. Review of functional electrical stimulation exercise equipment added to policy; this is considered investigational. (sk)
- 11/26/19 Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)
- 11/10/20 References added. Description and Policy Guidelines for Functional Neuromuscular Electrical Stimulation updated. Specialty Matched Consultant Advisory Panel review 10/21/2020. (sk)
- 6/1/21 Additional sections titled "Peripheral Subcutaneous Field Stimulation" and "Threshold Electrical Stimulation" added to policy. Related policies updated. Policy statement updated to read "Functional Neuromuscular Electrical Stimulation, Peripheral

Subcutaneous Field Stimulation, Neuromuscular Electrical Stimulation, and Threshold Electrical Stimulation are considered investigational for all applications". Medical Director review. Policy noticed 6/1/2021 for effective date 8/10/2021. (sk)

- 3/31/22 References added. Specialty Matched Consultant Advisory Panel review 10/20/2021. (sk)
- 5/3/22 References added. Specialty Matched Consultant Advisory Panel review 4/2022. Medical Director review 4/2022. No change to policy statement. (tt)
- 6/14/22 Added CPT code 0720T to Billing/Coding section. Effective 7/1/2022. (tt)
- 7/12/22 Updated CPT code under "Other Electrical Stimulation Devices" section for Percutaneous electrical nerve stimulation (PENS) (Code 64999; HCPCS Code E1399) and added the following statement "Providers may submit claims for these services using the unlisted code 64999. Providers should not be using 64553-64565, or 64590 to bill this service as these codes are not appropriate." No change to policy statement. Medical Director Review 6/2022. (tt)
- 5/2/23 References added. Specialty Matched Consultant Advisory Panel review 4/2023. Medical Director review 4/2023. No change to policy statement. (tt)
- 6/13/23 Added HCPCS code C1767 to Peripheral Subcutaneous Field Stimulation Billing/Coding section. (tt)
- 12/29/23 Added the following CPT codes to Peripheral Subcutaneous Field Stimulation Billing/Coding section: 64596, 64597, 64598, effective 1/1/2024. (tt)

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