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Description of Procedure or Service

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

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

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 neuromuscular electrical stimulation (NMES) is a method being developed to restore function to patients with damaged or destroyed nerve pathways through use of an orthotic device with microprocessor controlled electrical neuromuscular stimulation (neuroprosthesis).
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One application of functional neuromuscular electrical stimulation (NMES) 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 neural prosthetic devices have been developed for functional NMES in 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’ radio-frequency controlled NESS L300™, 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. This policy does not address these commercially available exercycles.

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
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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 NESS L300® received 510(k) marketing clearance in July 2006. 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.”

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

Functional 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).

***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 functional NMES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. Evidence on functional NMES for the upper limb in patients with spinal cord injury or stroke includes a few small case series. Interpretation of the evidence is limited by the small number of patients studied and lack of data demonstrating the utility of NMES outside the investigational setting. It is uncertain whether NMES can restore some upper-extremity function or improve quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic footdrop who receive functional NMES, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are functional outcomes and quality of life. For
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chronic poststroke footdrop, 2 large RCTs have shown improved patient satisfaction with NMES, but no significant difference between NMES and a standard ankle-foot orthosis in objective measures like walking. A small randomized trial examining neuromuscular stimulation for footdrop in patients with multiple sclerosis showed a reduction in falls (a clinically significant outcome) and improvement in patient satisfaction compared with an exercise program, but did not demonstrate a clinically significant benefit in walking speed. Studies in a larger number of patients are needed to obtain greater certainty about the generalizability of this health outcome. The literature on NMES for footdrop in children with cerebral palsy includes a systematic review of small studies with within-subject designs; additional study in a larger number of subjects is needed. Overall, there is insufficient evidence for some indications, and a lack of improvement in objective measures for others. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spinal cord injury at segments T4 to T12 who receive functional NMES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. No controlled trials were identified on functional NMES 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 these patients. 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 the effects of the technology on health outcomes.

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): 64565, 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.
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The mechanism of 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

No devices have been approved specifically for PSFS. PSFS is an off-label use of spinal cord stimulation devices that have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic pain.

Related policies:
Spinal Cord 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 the effects of the technology on health outcomes.

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: 64999

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.
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Scientific Background and Reference Sources

**Policy entitled: Therapeutic Electrical Stimulation (TES)**

Plan Consultant - 12/96

Physician Advisory Group Review 2/97


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)**


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; 12/18/02


**New Policy entitled: Electrical Stimulators, Neuromuscular**


Neurostimulation, Electrical


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

Senior Medical Director Review – 5/2010


Policy Name Change: Neurostimulation, Electrical


Medical Director – 6/2011


Medical Director – 1/2012

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


BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/14/2013
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BCBSA Medical Policy Reference Manual [Electronic Version], 8.03.01, 2/13/2014


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


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

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.


2/02 Coding format change.
8/03 Description and Benefits Application sections revised. Key words added.

Policy entitled: Functional Neuromuscular Stimulation (FNS)
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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.
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


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
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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)
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