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Neuromuscular Electrical Stimulator (NMES)
Corporate Medical Policy

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Document Precedence

BCBSVT Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with all terms, conditions and limitations of the subscriber contract. Benefit determinations are based in all cases on the applicable contract language. To the extent that there may be any conflict between Medical Policy and contract language, the contract language takes precedence.

Medical Policy

Description

Neuromuscular electrical stimulators (NMES) 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.

Functional 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.

Neural prosthetic devices consist of an orthotic and a microprocessor-based electronic stimulator with one or more channels for delivery of individual pulses through surface or implanted electrodes connected to the neuromuscular system. Microprocessor programs activate the channels sequentially or in unison to stimulate peripheral nerves and trigger muscle contractions to produce functionally useful movements that allow patients to sit, stand, walk, and grasp. Functional neuromuscular stimulators are closed loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters which are required for complex activities such as walking. These contrast with open loop systems, which are used for simple tasks such as muscle strengthening alone and typically in healthy individuals with intact neural control.

One application of functional 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 (quadraplegia). 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 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. The implantable Freehand System is no longer marketed in the U.S., though the company provides maintenance for devices already implanted. The Handmaster NMS I [neuromuscular stimulator] 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. The Handmaster NMS I system 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.

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 stroke or multiple sclerosis (MS). 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. Examples of such devices used for treatment of foot drop are the Innovative Neurotronics' (formerly NeuroMotion, Inc.) WalkAide®, Bioness' radiofrequency controlled NESS L300™, and the Odstock Foot Drop Stimulator. 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 Foot Drop Stimulator received 510(k) marketing clearance in 2005. The Bioness NESS L300 received 510(k) marketing clearance in July 2006. The FDA summaries for the devices state that they are intended to be used in patients with foot drop by assisting with ankle dorsiflexion during the swing phase of gait.

Another application of functional NMES 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.

To date, the Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval (PMA) from the U.S. Food and Drug Administration (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." 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 treatment of secondary dysfunction (e.g., muscle atrophy and alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways. These applications are not addressed in this policy.

Policy

Therapeutic NMES devices may be considered **medically necessary** for the treatment of adequately documented disuse atrophy when the nerve supply to the muscle is intact and results from listed conditions in which clinical improvement may be expected.

When requesting prior authorization for the use of NMES in disuse atrophy, the medical record must show supporting documentation of the member's diagnosis of disuse atrophy (based on physical exam) and electromyography (EMG) as a result of one of the following:

- Recent hip surgery until the patient begins physical therapy, or
- Prolonged (greater than 12 weeks) casting or splinting of a joint, or
- Contractures as a result of scarring of soft tissue from burns.
- Treatment to improve wrist and finger function and prevent or correct shoulder subluxation in persons with partial paralysis following stroke.

Use of neuromuscular electrical stimulation devices in the treatment of scoliosis (E0744) is considered **experimental/investigational.**

Use of neuromuscular electrical stimulation devices for motor disorders related to cerebral palsy is considered **experimental/investigational.**

Neuromuscular electrical stimulation devices for home use, for all other conditions, are considered **experimental/investigational.**

Functional neuromuscular stimulation (also known as Neuromuscular Electrical Stimulation (NMES), Functional Neuromuscular Stimulation (FNS), Functional Electrical Stimulation (FES), Electrical Neuromuscular Stimulation (ENS), or electromyography (EMG) triggered neuromuscular stimulation using any device is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes, but is not limited to, its use in the following situations:

- As a technique to provide ambulation in patients with spinal cord injury; or
- To provide upper or lower 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).
- As a treatment for pain.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

For New England Health Plan (NEHP) members an approved referral authorization is required.

Benefits for Federal Employee Program (FEP) members may vary. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure.

NMES requires a prescription from a physician.

Eligible Providers

Medical Doctor (M.D. or D.O.)
Durable Medical Equipment (DME) suppliers

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Related Policies

Durable Medical Equipment (DME)

Policy Implementation/Update information

5/2007 reviewed by the CAC
1/2008 annual review. No changes made. Reviewed by the CAC 5/2008
11/2011 Updated and Transferred to new format. Criteria for medically necessary use updated. New language concerning use for cerebral palsy as investigational. Clarification as to the difference between functional and therapeutic uses of NMES. References updated. Coding table updated to include new CPT codes for 2012. CPT and HCPSC investigational codes designations added to coding table.
1/2013-Description section updated to include FDA approved systems. New Investigational wording added. Codes updated, some codes moved to investigational (formally required PA). Approved by both the Medical Policy and Medical Policy and Provider Committees. Medical/ Clinical Coder reviewed. RLJ

Scientific Background and Reference Resources

A search of the literature was performed through October 2011. Although the evidence regarding NMES is limited, therapeutic NMES is an established treatment modality for patients with disuse atrophy where the nerve supply to the muscle is intact and volitional exercise is temporarily not possible as a result of the conditions listed in the Policy section.

References:

1. BCBSA Policy 1.01.19, Issue 2:2011, Threshold Electrical Stimulation as Treatment of Motor Disorders
2. BCBSA Policy 8.03.01, Issue 2:2011, Functional Neuromuscular Electrical Stimulation
3. Chaplin E. Functional neuromuscular stimulation for mobility in people with spinal cord injuries. The Parastep I System. J Spinal Cord Med 1996; 19(2):99-105.
4. Klose KJ, Jacobs PL, Broton JG et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep®1 Ambulation System: part 1. Ambulation performance and anthropometric measures. Arch Phys Med Rehabil 1997; 78(8):789-93.
5. Jacobs PL, Nash MS, Klose KJ et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep®1 Ambulation System: part 2. Effects on physiologic responses to peak arm ergometry. Arch Phys Med Rehabil 1997; 78(8):794-8.
6. Needham-Shropshire BM, Broton JG, Klose KJ et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep®1 Ambulation System: part 3. Arch Phys Med Rehabil 1997; 78(8):799-803.
7. Nash MS, Jacobs PL, Montalvo BM et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep®1 Ambulation System: part 5. Arch Phys Med Rehabil 1997; 78(8):808-14.
8. Guest RS, Klose J, Needham-Shropshire BM et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep®1 Ambulation System: part 4. Arch Phys Med Rehabil 1997; 78(8):804-7.
9. Graupe D, Kohn KH. Functional neuromuscular stimulator for short-distance ambulation by certain thoracic-level spinal-cord-injured paraplegics. Surg Neurol 1998; 50(3):202-7.
10. Brissot R, Gallien P, Le Bot MP et al. Clinical experience with functional electrical stimulation-assisted gait with Parastep in spinal cord-injured patients. Spine 2000; 25(4):501-8.
11. Sykes L, Ross ER, Powell ES et al. Objective measurement of use of the reciprocating gait orthosis (RGO) and the electrically augmented RGO in adult patients with spinal cord lesions. Prosthet Orthot Int 1996; 20(3):182-90.
12. Davis JA Jr, Triolo RJ, Uhlir J et al. Preliminary performance of a surgically implanted neuroprosthesis for standing and transfers – where do we stand? J Rehabil Res Dev 2001; 38(6):609-17.
13. Taylor P, Esnouf J, Hobby J. The functional impact of the Freehand System on tetraplegic hand function. Clinical Results. Spinal Cord 2002; 40(11):560-6.

14. Mulcahey MJ, Betz RR, Smith BT et al. Implanted functional electrical stimulation hand system in adolescents with spinal injuries: an evaluation. Arch Phys Med Rehabil 1997; 78(6):597-607.
15. Mulcahey MJ, Betz RR, Kozin SH et al. Implantation of the Freehand System during initial rehabilitation using minimally invasive techniques. Spinal Cord 2004; 42(3):146-55.
16. Hamid S, Hayek R. Role of electrical stimulation for rehabilitation and regeneration after spinal cord injury: an overview. Eur Spine J 2008; 17(9):1256-69.
17. Snoek GJ, IJzerman MJ, in 't Groen FA et al. Use of the NESS handmaster to restore handfunction in tetraplegia: clinical experiences in ten patients. Spinal Cord 2000; 38(4):244-9.
18. Alon G, McBride K. Persons with C5 or C6 tetraplegia achieve selected functional gains using a neuroprosthesis. Arch Phys Med Rehabil 2003; 84(1):119-24.
19. Alon G, McBride K, Ring H. Improving selected hand functions using a noninvasive neuroprosthesis in persons with chronic stroke. J Stroke Cerebrovasc Dis 2002; 11(2):99-106.
20. Taylor PN, Burridge JH, Dunkerley AL et al. Clinical use of the Odstock dropped foot stimulator: its effect on the speed and effort of walking. Arch Phys Med Rehabil 1999; 80(12):1577-83.
21. Hausdorff JM, Ring H. Effects of a new radio frequency-controlled neuroprosthesis on gait symmetry and rhythmicity in patients with chronic hemiparesis. Am J Phys Med Rehabil 2008; 87(1):4-13.
22. Laufer Y, Hausdorff JM, Ring H. Effects of a foot drop neuroprosthesis on functional abilities, social participation, and gait velocity. Am J Phys Med Rehabil 2009; 88(1):14-20.
23. Ring H, Treger I, Gruendlinger L et al. Neuroprosthesis for footdrop compared with ankle-foot orthosis: effects on postural control during walking. J Stroke Cerebrovasc Dis 2009; 18(1):41-7.
24. van Swigchem R, Vloothuis J, den Boer J et al. Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subjects study of patients' satisfaction, walking speed and physical activity level. J Rehabil Med 2010; 42(2):117-21.
25. Stein RB, Everaert DG, Thompson AK et al. Long-term therapeutic and orthotic effects of a foot drop stimulator on walking performance in progressive and nonprogressive neurological disorders. Neurorehabil Neural Repair 2010; 24(2):152-67.
26. Barrett CL, Mann GE, Taylor PN et al. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. Mult Scler 2009; 15(4):493-504.
27. Sheffler LR, Hennessey MT, Knutson JS et al. Neuroprosthetic effect of peroneal nerve stimulation in multiple sclerosis: a preliminary study. Arch Phys Med Rehabil 2009; 90(2):362-5.
28. National Institute for Health and Clinical Excellence. Functional electrical stimulation for drop foot of central neurological origin. January 2009. Available online at: http://www.nice.org.uk/nicemedia/pdf/IPG278Guidance.pdf. Last accessed March 2011.

29. Centers for Medicare and Medicaid Services. National Coverage Determination for neuromuscular electrical stimulation (NMES) (160.12). Available online at: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=160.12&ncd_version=2&basket=ncd%3A160%2E12%3A2%3ANeuromuscular+Electrical+Stimulaton+%28NMES%29. Last accessed March 2011.

Approved by BCBSVT Medical Directors **Date Approved**

Spencer Borden MD
Chair, Medical Policy Committee

Robert Wheeler MD
Chief Medical Officer

Attachment I
Coding Table & Instructions

Code Type	Number	Brief Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
CPT	63650	Percutaneous implantation of neurostimulator electrode array, epidural	Prior Approval Required
CPT	63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural	Prior Approval Required
CPT	63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	Prior Approval Required
CPT	63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed	Prior Approval Required

CPT	63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	Prior Approval Required
CPT	63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed	Prior Approval Required
CPT	63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling	Prior Approval Required
CPT	63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver	Prior Approval Required
CPT	64577	Incision for implantation of neurostimulator electrodes; autonomic nerve	Prior Approval Required
CPT	64580	Incision for implantation of neurostimulator electrodes; neuromuscular	Prior Approval Required
CPT	64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)	Prior Approval Required

CPT	95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude & duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance & patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming	Prior Approval Required
CPT	95972	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour	Prior Approval Required

CPT	95973	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)	Prior Approval Required
HCPCS	A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)	Prior Approval Required
HCPCS	E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patients skin by layers of fabric)	Prior Approval Required
HCPCS	E0745	Neuromuscular stimulator, electronic shock unit	Prior Approval Required
HCPCS	L8680	Implantable neurostimulator electrode (with any number of contact points)	Prior Approval Required
HCPCS	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	Prior Approval Required
HCPCS	L8682	Implantable neurostimulator radiofrequency receiver	Prior Approval Required
HCPCS	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	Prior Approval Required

HCPCS	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	Prior Approval Required
HCPCS	L8686	Implantable neurostimulator pulse generator	Prior Approval Required
HCPCS	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	Prior Approval Required
HCPCS	L8688	Implantable neurostimulator pulse generator, dual array , non-rechargeable, includes extension	Prior Approval Required
HCPCS	L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	Prior Approval Required
The following codes will be denied as Investigational			
CPT	64575	Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)	
CPT	64585	Revision or removal of peripheral neurostimulator electrodes	
CPT	95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude & duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance & patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming	

CPT	0282T	Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar; for trial, including removal at the conclusion of trial period	
CPT	0283T	Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar; permanent, with implantation of a pulse generator	
CPT	0284T	Revision or removal of pulse generator or electrodes, including imaging guidance, when performed, including addition of new electrodes, when performed	
CPT	0285T	Electronic analysis of implanted peripheral subcutaneous field stimulation pulse generator, with reprogramming when performed	
HCPCS	E0762	Transcutaneous electrical joint stimulation device system	
HCPCS	E0764	Functional neuromuscular stimulation, 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	
HCPCS	E0744	Neuromuscular stimulator for scoliosis	

HCPCS	E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified	
Type of Service		Surgery, Durable Medical Equipment	
Place of Service		Outpatient	