

Protocol

Functional Neuromuscular Electrical Stimulation

(80301)

Medical Benefit		Effective Date: 07/01/16	Next Review Date: 05/18
Preauthorization	Yes	Review Dates: 03/07, 05/08, 05/09, 01/10, 01/11, 01/12, 01/13, 05/13, 05/14, 05/15, 05/16, 05/17	

Preauthorization is required for Medicare Advantage members; for all other products this protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With loss of hand function due to spinal cord injury or stroke	Interventions of interest are: <ul style="list-style-type: none">• Functional neuromuscular electrical stimulation	Comparators of interest are: <ul style="list-style-type: none">• Standard care	Relevant outcomes include: <ul style="list-style-type: none">• Functional outcomes• Quality of life
Individuals: <ul style="list-style-type: none">• With chronic footdrop	Interventions of interest are: <ul style="list-style-type: none">• Functional neuromuscular electrical stimulation	Comparators of interest are: <ul style="list-style-type: none">• Standard care• Ankle-foot orthosis	Relevant outcomes include: <ul style="list-style-type: none">• Functional outcomes• Quality of life
Individuals: <ul style="list-style-type: none">• With spinal cord injury at segments T4 to T12	Interventions of interest are: <ul style="list-style-type: none">• Functional neuromuscular electrical stimulation	Comparators of interest are: <ul style="list-style-type: none">• Standard care	Relevant outcomes include: <ul style="list-style-type: none">• Functional outcomes• Quality of life

Description

Functional neuromuscular electrical stimulation (NMES) involves the use of an orthotic device with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function to patients with damaged or destroyed nerve pathways (e.g., spinal cord injury, stroke, multiple sclerosis, cerebral palsy).

Summary of Evidence

For individuals who have loss of hand 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 chronic poststroke footdrop, two 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.

Policy

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).

Medicare Advantage

For Medicare Advantage NMES/FES is **medically necessary** for spinal cord injury (SCI) patients for walking, who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months. (See Medicare Advantage Policy Guidelines)

NMES/FES for walking is **medically necessary** in SCI patients with all of the following characteristics:

1. Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);
2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
3. Persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
4. Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

5. Persons that can transfer independently and can demonstrate independent standing tolerance for at least three minutes;
6. Persons that can demonstrate hand and finger function to manipulate controls;
7. Persons with at least six-month post recovery spinal cord injury and restorative surgery;
8. Persons with hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
9. Persons who have demonstrated a willingness to use the device long-term.

NMES/FES for walking is **not medically necessary** in SCI patient with any of the following:

1. Persons with cardiac pacemakers;
2. Severe scoliosis or severe osteoporosis;
3. Skin disease or cancer at area of stimulation;
4. Irreversible contracture; or
5. Autonomic dysreflexia.

It might be **medically necessary** for certain patients receiving NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients' skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be considered **medically necessary** only when:

1. It has received permission or approval for marketing by the Food and Drug Administration;
2. It has been prescribed by a physician for use in delivering covered NMES treatment; and
3. One of the medical indications outlined below is met:
 - The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
 - The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
 - The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

Medicare Advantage Policy Guidelines

The trial period of physical therapy will enable the physician treating the patient for his or her spinal cord injury to properly evaluate the person's ability to use these devices frequently and for the long term. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program.

The only settings where therapists with the sufficient skills to provide these services are employed are inpatient hospitals; outpatient hospitals; comprehensive outpatient rehabilitation facilities; and outpatient rehabilitation facilities.

The goal of physical therapy must be to train SCI patients on the use of neuromuscular electrical stimulation/ functional electrical stimulation (NMES/FES) devices to achieve walking, not to reverse or retard muscle atrophy.

Background

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 that provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities (e.g., walking). These systems are contrasted with open-loop systems, which are used for simple tasks (e.g., 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 (quadriplegia). NeuroControl Corp. developed the Freehand System, an implantable upper-extremity neuroprosthesis, to improve ability to grasp, hold, and release objects for patients with tetraplegia 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 system) is an upper-extremity device that uses a forearm splint and surface electrodes. The device, controlled by a user-activated button, is intended to provide hand function (fine finger grasping, larger palmar grasping) for patients with C5 tetraplegia or stroke.

Other neural prosthetic devices have been developed to provide functional NMES for patients with footdrop. Footdrop 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 footdrop are the Innovative Neurotronics' (formerly NeuroMotion Inc.) WalkAide, Bioness's radiofrequency controlled NESS L300, MyGait (Otto Bock HealthCare), and the OFDS (Odstock Foot Drop Stimulator). An implantable peroneal nerve stimulator system (ActiGait®) is being developed in Europe.

Another application of functional electrical stimulation is to provide patients with spinal cord injury the ability to stand and walk. Generally, only spinal cord injury patients with spinal lesions from T4 to T12 are considered candidates for ambulation systems. Lesions at T1 to 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 electric impulses are controlled by a computer microchip attached to the patient's belt, which 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 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.

Other devices, such as the ReGrasp (Rehabtronics), are used for rehabilitation rather than home use. Neuromuscular stimulation is also proposed for motor restoration in hemiplegia and treatment of secondary dysfunction (e.g., muscle atrophy, alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways. These applications are not addressed herein.

Regulatory Status

In 1997, the Freehand® System (NeuroControl Corp.) was approved by the U.S. Food and Drug Administration (FDA) through the premarket 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 marketing by FDA through the 510(k) process for use in maintaining or improving range of motion, reducing muscle spasm, preventing or retarding muscle atrophy, providing muscle re-education, and improving circulation (K022776); 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. FDA product code: GZC.

The WalkAide® System (Innovative Neurotronics) was first cleared for marketing by FDA through the 510(k) process in the 1990s (K052329); the current version of the WalkAide® device received 510(k) marketing clearance in September 2005. The ODFS (Odstock Dropped Foot Stimulator) received 510(k) marketing clearance in 2005 (K050991). The NESS L300® (Bioness Inc.) was cleared for marketing by FDA through the 510(k) process in July 2006. The MyGait® Stimulation System (Otto Bock HealthCare) received 510(k) marketing clearance in 2015 (K141812). FDA summaries of the devices state that they are intended for patients with footdrop by assisting with ankle dorsiflexion during the swing phase of gait. FDA product code: GZI.

To date, the Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive PMA from 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.” FDA product code: MKD.

Related Protocols

Microprocessor-Controlled Prostheses for the Lower Limb

Myoelectric Prosthesis Components for the Upper Limb

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Mulcahey MJ, Betz RR, Kozin SH, et al. Implantation of the Freehand System during initial rehabilitation using minimally invasive techniques. *Spinal Cord*. Mar 2004; 42(3):146-155. PMID 15001979
2. 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*. Jun 1997; 78(6):597-607. PMID 9196467
3. Taylor P, Esnouf J, Hobby J. The functional impact of the Freehand System on tetraplegic hand function. *Clinical Results. Spinal Cord*. Nov 2002; 40(11):560-566. PMID 12411963
4. Venugopalan L, Taylor PN, Cobb JE, et al. Upper limb functional electrical stimulation devices and their man-machine interfaces. *J Med Eng Technol*. 2015; 39(8):471-479. PMID 26508077
5. Snoek GJ, MJ IJ, in't Groen FA, et al. Use of the NESS handmaster to restore handfunction in tetraplegia: clinical experiences in ten patients. *Spinal Cord*. Apr 2000; 38(4):244-249. PMID 10822395
6. Alon G, McBride K. Persons with C5 or C6 tetraplegia achieve selected functional gains using a neuroprosthesis. *Arch Phys Med Rehabil*. Jan 2003; 84(1):119-124. PMID 12589632
7. Alon G, McBride K, Ring H. Improving selected hand functions using a noninvasive neuroprosthesis in persons with chronic stroke. *J Stroke Cerebrovasc Dis*. Mar-Apr 2002; 11(2):99-106. PMID 17903863
8. Bethoux F, Rogers HL, Nolan KJ, et al. The effects of peroneal nerve functional electrical stimulation versus ankle-foot orthosis in patients with chronic stroke: a randomized controlled trial. *Neurorehabil Neural Repair*. Sep 2014; 28(7):688-697. PMID 24526708
9. Kluding PM, Dunning K, O'Dell MW, et al. Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. *Stroke*. Jun 2013; 44(6):1660-1669. PMID 23640829
10. O'Dell MW, Dunning K, Kluding P, et al. Response and prediction of improvement in gait speed from functional electrical stimulation in persons with poststroke drop foot. *PM R*. Jul 2014; 6(7):587-601; quiz 601. PMID 24412265
11. 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*. Apr 2009; 15(4):493-504. PMID 19282417
12. Esnouf JE, Taylor PN, Mann GE, et al. Impact on activities of daily living using a functional electrical stimulation device to improve dropped foot in people with multiple sclerosis, measured by the Canadian Occupational Performance Measure. *Mult Scler*. Sep 2010; 16(9):1141-1147. PMID 20601398
13. 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*. Feb 2010; 24(2):152-167. PMID 19846759
14. Cauraugh JH, Naik SK, Hsu WH, et al. Children with cerebral palsy: a systematic review and meta-analysis on gait and electrical stimulation. *Clin Rehabil*. Nov 2010; 24(11):963-978. PMID 20685722
15. Prosser LA, Curatalo LA, Alter KE, et al. Acceptability and potential effectiveness of a foot drop stimulator in children and adolescents with cerebral palsy. *Dev Med Child Neurol*. Nov 2012; 54(11):1044-1049. PMID 22924431
16. Meilahn JR. Tolerability and effectiveness of a neuroprosthesis for the treatment of footdrop in pediatric patients with hemiparetic cerebral palsy. *PM R*. Jun 2013; 5(6):503-509. PMID 23313040
17. Chaplin E. Functional neuromuscular stimulation for mobility in people with spinal cord injuries. The Parastep I System. *J Spinal Cord Med*. Apr 1996; 19(2):99-105. PMID 8732878
18. 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*. Aug 1997; 78(8):789-793. PMID 9344294

19. 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 physiological responses to peak arm ergometry. *Arch Phys Med Rehabil.* Aug 1997; 78(8):794-798. PMID 9344295
20. 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. Lack of effect on bone mineral density. *Arch Phys Med Rehabil.* Aug 1997; 78(8):799-803. PMID 9344296
21. Guest RS, Klose KJ, Needham-Shropshire BM, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 4. Effect on physical self-concept and depression. *Arch Phys Med Rehabil.* Aug 1997; 78(8):804-807. PMID 9344297
22. 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. Lower extremity blood flow and hyperemic responses to occlusion are augmented by ambulation training. *Arch Phys Med Rehabil.* Aug 1997; 78(8):808-814. PMID 9344298
23. Graupe D, Kohn KH. Functional neuromuscular stimulator for short-distance ambulation by certain thoracic-level spinal-cord-injured paraplegics. *Surg Neurol.* Sep 1998; 50(3):202-207. PMID 9736079
24. Brisson R, Gallien P, Le Bot MP, et al. Clinical experience with functional electrical stimulation-assisted gait with Parastep in spinal cord-injured patients. *Spine (Phila Pa 1976).* Feb 15 2000; 25(4):501-508. PMID 10707398
25. 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.* Dec 1996; 20(3):182-190. PMID 8985998
26. Davis JA, Jr., Triolo RJ, Uhler J, et al. Preliminary performance of a surgically implanted neuroprosthesis for standing and transfers--where do we stand? *J Rehabil Res Dev.* Nov-Dec 2001; 38(6):609-617. PMID 11767968
27. Rohde LM, Bonder BR, Triolo RJ. Exploratory study of perceived quality of life with implanted standing neuroprostheses. *J Rehabil Res Dev.* 2012; 49(2):265-278. PMID 22773528
28. Triolo RJ, Bailey SN, Miller ME, et al. Longitudinal performance of a surgically implanted neuroprosthesis for lower-extremity exercise, standing, and transfers after spinal cord injury. *Arch Phys Med Rehabil.* May 2012; 93(5):896-904. PMID 22541312
29. National Institute for Health and Clinical Excellence. Functional electrical stimulation for drop foot of central neurological origin (IPG278). 2009; <http://www.nice.org.uk/nicemedia/pdf/IPG278Guidance.pdf>. Accessed July 25, 2016.
30. Centers for Medicare and Medicaid Services. National Coverage Determination for neuromuscular electrical stimulation (NMES) (160.12). October 1, 2006; http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=175&ncdver=2&DocID=160.12&ncd_id=160.12&ncd_version=2&basket=ncd%2525. Accessed July 25, 2016.
31. National Coverage Determination (NCD) for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13), Effective Date of this Version 7/14/1988.
32. National Government Services, Inc. Local Coverage Determination (LCD): Outpatient Physical and Occupational Therapy Services (L33631), Revision Effective Date for services performed on or after 01/01/2017.