



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

## Functional Neuromuscular Electrical Stimulation

**Policy Number:** 8.03.01

**Origination:** 10/1988

**Last Review:** 4/2014

**Next Review:** 4/2015

### **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for functional neuromuscular stimulation. This is considered investigational.

Neuromuscular stimulation is excluded in contracts that contain an exclusion for electrical stimulation. Verify benefits to determine whether this is a benefit exclusion or investigational.

### **When Policy Topic is covered**

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Not Applicable

### **When Policy Topic is not covered**

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Neuromuscular (electrical) 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).

Neuromuscular electrical stimulation (NMES) is considered **investigational** for all other indications, including rehabilitating leg muscles after anterior cruciate ligament surgery, strengthening leg muscles after hip fracture or hip replacement surgery, strengthening muscles of the arm after spinal cord injury, improving motor function in patients with cerebral palsy, and providing exercise for patients with severe physical limitations due to chronic osteoarthritis, obstructive pulmonary disease or chronic heart failure.

### **Considerations**

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Claims or prior authorization requests may come in under the product trade name of Parastep® or a device called a reciprocating gait orthosis (RGO) with electrical stimulation.

This policy does not refer to commercially available exercycles that use electrical muscle stimulation technology as a means of physical therapy and exercise for spinal cord injury patients. These exercycles are sometimes called functional neuromuscular exercisers. The goals for using these devices may be 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. Plans may wish to review their policies on durable medical equipment and physical therapy services when reviewing electrical muscle stimulation exercycles. Some might consider this a physical therapy modality.

Neuromuscular stimulation to prevent atrophy of skeletal muscles resulting from disuse due to disease, trauma or surgery is addressed in the separate policy.

### **Description of Procedure or Service**

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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).

## **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, 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 are contrasted 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 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 (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 cerebral palsy, 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 drop foot by assisting with ankle dorsiflexion during the swing phase of gait.

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.

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.

### **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 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.

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### **Rationale**

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This policy was created in 1996 and updated periodically using the MEDLINE database. The most recent update was performed through January 7, 2014. Following is a summary of key studies to date.

#### **Ambulation in Patients with Spinal Cord Injury**

The clinical impact of the Parastep® device rests on identification of clinically important outcomes. The primary outcome of the Parastep device, and the main purpose of its design, is to provide a degree of ambulation that improves the patient’s ability to complete the activities of daily living, or positively affect the patient’s quality of life. Physiologic outcomes (ie, conditioning, oxygen uptake, etc.) have also been reported, but these are intermediate, short-term outcomes, and it is not known whether similar or improved results could be attained with other training methods. In addition, the results are reported for mean peak values, which may or may not be a consistent result over time. The effect of the Parastep on physical self-concept and depression are secondary outcomes and similar to the physiologic outcomes; interpretation is limited due to lack of comparison with other forms of training.

The largest study was conducted by Chaplin, who reported on the ambulation outcomes using the Parastep I in 91 patients. (1) Of these 91 patients, 84 (92%) were able to take steps and 31 (34%) were able to eventually ambulate without assistance from another person. Duration of use was not reported. Other studies on the Parastep device include a series of 5 studies from the same group of

investigators, which focused on different outcomes in the same group of 13–16 patients. (2-6) In a 1997 study, Guest et al reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury. (5) All patients underwent 32 training sessions prior to measuring ambulation. The group's mean peak distance walked was 334 meters, but there was wide variability, as evidenced by a standard deviation of 402 meters. The mean peak duration of walking was 56 minutes, again with wide variability, evidenced by a standard deviation of 46 minutes. It should be noted that peak measures reflect the best outcome over the period evaluated; peak measures may be an inconsistent, one-time occurrence for the individual patient. The participants also underwent anthropomorphic measurements of various anatomic locations. Increases in thigh and calf girth, thigh cross-sectional area, and calculated lean tissue were all statistically significant. The authors emphasize that the device is not intended to be an alternative to a wheelchair, and thus other factors such as improved physical and mental well-being should be considered when deciding whether or not to use the system. The same limitations were noted in a review article by Graupe and Kohn, who state that the goal for ambulation is for patients to get out of the wheelchair at will, stretch, and take a few steps every day. (7)

Jacobs et al reported on physiologic responses related to use of the Parastep device. (3) There was a 25% increase in time to fatigue and a 15% increase in peak values of oxygen uptake, consistent with an exercise training effect. There were no significant effects on arm strength. Needham-Shropshire et al reported no relationship between use of the Parastep device and bone mineral density, although the time interval between measurements (12 weeks) and the precision of the testing device may have limited the ability to detect a difference. (4) Nash et al reported that use of the Parastep device was associated with an increase in arterial inflow volume to the common femoral artery, perhaps related to the overall conditioning response to the Parastep. (6) Also, Guest et al reported significant improvements in physical self-concept and decreases in depression scores. (5) Finally, it should be noted that evaluations of the Parastep device were performed immediately following initial training or during limited study period durations. (1, 8-10) There are no data regarding whether patients remained compliant and committed with long-term use.

Brissot et al reported independent ambulation was achieved in 13 of 15 patients, with 2 patients withdrawing from the study. (8) In the home setting, 5 of the 13 patients continued using the device for physical fitness, but none used it for ambulation. Sykes et al found low use of a reciprocating gait orthosis device with or without stimulation over an 18-month period. (10) In addition, the more recent Davis et al study of a surgically implanted neuroprosthesis for standing and transfers after spinal cord injury showed mixed usability/preference scale results for ambulation with device assistance versus conventional transfers in 12 patients followed up for a 12-month period post-discharge. (9) Therefore, the advantage of using device assistance could not be evaluated.

The effect of a surgically implanted neuroprosthesis on exercise, standing, transfers, and quality of life was reported in 2012. (11, 12) This study was supported by the U.S. Department of Veterans Affairs, the Office of Orphan Product Development of FDA, the New York State Department of Health, and the National Center for Research Resources of the National Institutes of Health. The device is not commercially available at this time.

Conclusions. As stated by various authors, the Parastep system is not designed to be an alternative to a wheelchair and offers, at best, limited, short-term ambulation. Final health outcomes, such as ability to perform activities of daily living or quality of life, have not been reported.

## **Functional NMES (Neuromuscular Electrical Stimulation) of the Upper Extremity**

### Spinal Cord Injury

Most of the early published evidence for upper extremity devices to restore function in patients with spinal cord injuries report experience with the Freehand System, an implantable device that is no longer marketed in the U.S. (13-15) The device is controlled through a joystick on the shoulder or wrist. A disadvantage of this system is that additional surgery is required to repair hardware failures. The

published studies, all case series with fewer than 10 subjects, suggest that the device may give patients the ability to grasp and release objects and independence or greater independence in such activities of daily living as using a fork or the telephone in the study setting. User satisfaction was generally high, and most subjects reported continued use of the device at home, although details of specific activities or frequency of use at home are not provided. In a review of the role of electrical stimulation for rehabilitation and regeneration after spinal cord injury, Hamid and Hayek report that the company which marketed the Freehand System in the U.S. no longer manufactures new devices. (16)

Use of the Handmaster NMS I was reported in a series of 10 patients with cervical spinal cord injuries. (17) After 2 months of training, performance on a defined set of tasks and one or more tasks chosen by the patient was evaluated. In 6 patients, a stimulated grasp and release with either one or both grasp modes (key- and palmar pinch) of the Handmaster was possible. Four patients could perform the set of tasks using the Handmaster, while they were not able to do so without the Handmaster. Eventually, one patient continued using the Handmaster during activities of daily living (ADLs) at home. In another study using the Handmaster device, 7 subjects with C5 or C6 spinal cord injury practiced using the device daily on one of their paralyzed hands to regain the ability to grasp, hold, and release objects. (18) They were observed 2 to 3 times weekly for 3 weeks, and their ability to pick up a telephone, eat food with a fork, and perform an individually selected ADL task plus 2 grasp, hold, and release tasks was evaluated. At the end of the study, all 7 subjects were successful at using the device in the studied ADLs and grasp, hold, and release tasks. Improvements occurred in secondary measures of grip strength, finger linear motion, and Fugl-Meyer (developed to assess sensory-motor recovery after stroke) scores.

Hamid notes that, with either device, there is a time delay of 1-2 seconds between command generation and execution of grasp function that interferes with the speed with which the patient can grasp and release objects.

### Stroke

Alon et al, reporting on a case series of 29 patients, investigated whether the Handmaster system could improve selected hand function in persons with chronic upper extremity paresis following stroke. (19) The main outcome measures were 3 ADL tasks: lifting a 2-handled pot, holding a bag while standing with a cane, and another ADL chosen by the patient. Secondary measures included lifting a 600-gram weight, grip strength, electrically induced finger motion, Fugl-Meyer spherical grasp, and perceived pain scale. At the end of the 3-week study period, the percent of successful trials compared with baseline were: lifting pot, 93% versus 0%, lifting 600-gram weight, 100% versus 14%, and lifting bag, 93% versus 17% - all respectively. All subjects performed their selected ADL successfully and improved their Fugl-Meyer scores using the neuroprosthesis.

Conclusions. Interpretation of the evidence for upper extremity neuroprostheses for patients with spinal cord injuries or poststroke is limited by the small number of subjects and lack of data demonstrating its utility outside the study setting. The available evidence is insufficient to conclude that NMES improves outcomes by providing some upper extremity function.

## **Functional NMES for Chronic Foot Drop**

### Stroke and Spinal Cord Injury

Randomized Controlled Trials. FASTEST (NCT01138995) is an industry-sponsored single-blinded multicenter trial that randomized 197 patients to 30 weeks of a foot drop stimulator (NESS L300) or a conventional ankle-foot orthosis (AFO). (20) The AFO group received transcutaneous electrical nerve stimulation at each physical therapy visit during the first 2 weeks to provide a sensory control for stimulation of the peroneal nerve in the NESS L300 group. Evaluation by physical therapists who were blinded to group assignment found that both groups improved gait speed and other secondary outcome measures over time, with similar improvement in the 2 groups. There were no between-group

differences in the number of steps per day at home, which were measured by an activity monitor over a week. User satisfaction was higher with the foot drop stimulator.

*Prospective Crossover Trials.* A multicenter within-subject crossover trial of the WalkAid foot drop stimulator versus conventional AFO was published in 2013. (21) Patients who had a stroke within the previous 12 months and residual foot drop but no prior experience with an orthotic device were randomly assigned to WalkAid followed by AFO (6 weeks each, n=38), AFO followed by WalkAid (n=31), or AFO for 12 weeks (n=24). Walking tests were performed both with and without a device at 0, 3, 6, 9, and 12 weeks. The orthotic effect of the device is considered to be the immediate effect of NMES measured at any of the time points with the stimulator on compared with off. The therapeutic effect is the improvement over time (improvement in neuromuscular function) measured under the same conditions (ie, stimulator on versus on or stimulator off versus off) at different time points. The physiologic cost index (PCI), which is an indication of the amount of effort in walking, is assessed by the difference between resting heart rate and heart rate during walking, divided by the average walking speed. Both devices had significant orthotic (on-off difference) and therapeutic (changes over time when off) effects. The AFO had a greater orthotic effect on walking speed (figure 8 and 10-meter), while the WalkAid tended to have a greater therapeutic effect. The orthotic effect on PCI was significantly higher with an AFO than the WalkAid. Users felt equally safe with the 2 devices. Seventy percent preferred to keep the WalkAid after the 12-week study.

Van Swigchem et al published a within-subject comparison of a functional neuromuscular electrical stimulation (NMES) device (NESS L300) and AFO in 26 patients with chronic (>6 months) poststroke foot drop in 2010. (22) Baseline walking speed on a 10-meter walkway was assessed with the patient's custom-made AFO; physical activity at home was measured with a pedometer and averaged over 7 days, and satisfaction with the device was assessed with a "purpose-designed" 5-point questionnaire. After a 2-week period of adaptation to the NESS L300, walking speed was assessed with both the AFO and the NMES devices. For the next 6 weeks, patients increased use of the NMES device to the whole day, using the AFO 1 hour a day to maintain familiarity of walking with this device. At the end of the study, walking speed was assessed with both the AFO and the NMES devices, while activity at home and satisfaction were assessed for the NMES device. Two patients dropped out of the study due to discomfort from the electrical stimulation (n=1) and skin reaction to the electrodes (n=1). The remaining 24 patients provided an average satisfaction rating of 3.0 (neutral) for the AFO and 4.0 (satisfied) for the NMES device regarding comfort to wear, appearance, quality of gait, walking distance, effort of walking, and stability during gait. The objective measures of walking speed (1.02 for the AFO and 1.03 for NMES) and steps per day (5541 for the AFO and 5733 for NMES) were not significantly different for the 2 devices.

*Uncontrolled Case Series.* In 1999, Taylor et al reported a retrospective study on the clinical use of the Odstock dropped foot stimulator in 151 patients with chronic foot drop resulting from an upper motor lesion. (23) This retrospective study included 27 age-matched able-bodied controls and 140 patients (93%) who used the device for at least 4 1/2 months (111 patients with chronic foot drop due to stroke, 21 patients with multiple sclerosis [MS, described next], and 8 patients with incomplete spinal cord injury). The average time since stroke was 5.4 years. Walking speed was assessed on a 10-meter course. In stroke patients, the immediate (orthotic) effect of the stimulation was an increase in walking speed of 12% and a decrease in PCI of 18%. An improvement over time was also observed, with an increase in walking speed of 14% and a reduction of PCI of 19%, suggesting a therapeutic, as well as orthotic effect for this group.

Three reports from Israel described the effects of the NESS L300™ for post-stroke foot drop. Hausdorff and Ring report on gait symmetry and rhythmicity in 24 patients with chronic hemiparesis whose walking was impaired by foot drop. (24) Subjects increased time wearing the prosthesis from 1 hour per day to all day over a 4-week period, then wore it all day for 4 weeks. All 24 patients reported, in response to a yes/no question, that they increased their physical activities (not quantified) and had greater confidence in walking on inclines and/or uneven ground while wearing the prosthesis. Fourteen subjects recalled one or more falls occurring in the 2 months before the study, and no subject reported

falling while wearing the prosthesis. Laufer et al report a repeated measures follow-up of 16 patients with chronic hemiparesis who used the prosthesis for 1 year and were available for follow-up. (25) Outcome measures included the Short Version and the Participation domain of the Stroke Impact Scale. Gains of 18% in physical functioning and 25% in participation in community life were attained 2 months after application of the device and maintained at 1 year. In a study by Ring et al, 15 patients with chronic hemiparesis from stroke or traumatic brain injury who regularly used an ankle-foot orthosis that was adapted to the neuroprosthesis increased their daily use while using their ankle-foot orthosis the remainder of the day. (26) Outcomes related to ADL, safety, or quality of life were not reported.

In 2010, Stein et al reported improvements in both the orthotic and therapeutic effects of NMES in 41 patients with chronic nonprogressive foot drop (26 stroke, 9 spinal cord injury, 3 surgical complication, 2 head injury, and 1 cerebral palsy) and 32 patients with progressive foot drop (described in more detail following) after 1, 2, 3, 6, 9, and 11 months of use. (27) With the stimulator on compared with off (orthotic effect), walking speed improved by 5% for a figure 8 (0.59 vs 0.56 m/s) and 6% for a 10-meter test (0.80 vs 0.76 m/s). With the stimulator off, walking speed at 3 months had improved by 17% for a figure 8 (0.56 vs 0.48 m/s) and 12% for a 10-meter test (0.76 vs 0.68 m/s – all respectively) compared with baseline. The combined (orthotic and therapeutic) improvement in walking speed over the 3 months was 23% for the figure 8 (0.59 vs 0.48 m/s) and 18% for the 10-meter test (0.80 vs 0.68 m/s – both respectively).

### Multiple Sclerosis

The 1999 study by Taylor et al described earlier included 21 patients with MS. This group showed a 7% decrease in walking speed and a 16% increase in PCI over the course of the study when not using the Odstock dropped foot stimulator (absence of a therapeutic effect), while use of the stimulator (orthotic effect) resulted in an increase in walking speed of 16% and a decrease in PCI of 24%.

In 2009, a randomized controlled trial (RCT) of functional NMES to improve walking performance in patients with MS was published by Barrett et al. (28) Fifty-three patients with secondary progressive MS and unilateral dropped foot were randomized to an 18-week program of either NMES of the common peroneal nerve using a single channel Odstock Dropped Foot Stimulator or a home exercise program, and assessed at 6, 12, and 18 weeks. Patients in the stimulator group were encouraged to wear the device most of the day, switching it on initially for short walks and increasing daily for 2 weeks, after which they could use the device without restriction. Subjects in the control group were taught a series of exercises tailored to the individual to be done twice daily. The primary outcome measure was walking speed over a 10-meter distance. Two secondary outcome measures were energy efficiency based on increase in heart rate during walking and walking distance in 3 minutes. Six subjects in the NMES group and 3 in the exercise group dropped out very early in the study, leaving 20 in the NMES group and 24 in the exercise group. In the NMES group, mean changes between baseline and 18-week measures were nonsignificant for all 3 outcome measures, both with and without stimulation. However, within the NMES group, when mean values for walking speed and distance walked were compared with and without stimulation, outcomes were significantly better with stimulation. In the exercise group, increases in walking speed over 10 meters and distance walked in 3 minutes were highly significant,  $p=0.001$  and  $p=0.005$  respectively. At 18 weeks, the exercise group walked significantly faster than the NMES group ( $p=0.028$ ). The authors note a number of limitations of their study: power calculations were based on the 10-meter walking speed measure only and indicated that 25 subjects would be required in each group, patients were highly selected, clinical assessors also provided treatment (issues with blinding), and the validity and reliability of the 3-minute walk test have not been confirmed (fatigue prevented use of the validated 6-minute test). In addition, subjects in the exercise group were told they would receive a stimulator at the end of the trial, which may have impacted adherence to the exercise regimen, as well as retention in the trial. The authors concluded that “while a simple program of home exercise therapy appears to significantly increase walking speed and endurance over an 18-week intervention period, single channel common peroneal stimulation does not. However, it does appear to have a significant orthotic benefit, resulting in significantly increased walking speed and endurance when performance without stimulation is compared to performance with stimulation.”

A 2010 publication by the same group of investigators reported the impact of 18 weeks of physiotherapy exercises or the Odstock Dropped Foot Stimulator on ADL. (29) Results of 53 patients from the trial previously described were reported, using the Canadian Occupational Performance Measure (COPM). The COPM is a validated semistructured interview that was originally designed to assist the design of occupational therapy interventions. The interviews at baseline identified 265 problems of which 260 activities were related to walking and mobility. Subjective evaluation at 18 weeks showed greater improvements in performance and satisfaction scores in the NMES group (35% of problems had an increased score of 2 or more) than the exercise group (17% of problems had an increased score of 2 or more). The median satisfaction rating improved from 2.2 to 4.0 in the NMES group and remained stable (from 2.6 to 2.4) in the exercise group. The median number of falls recorded per patient over the 18-week study period was 5 in the NMES group and 18 in the exercise group. About 70% of the falls occurred while not using the NMES device or an ankle-foot orthotic device.

In a preliminary study, Sheffler et al compared functional ambulation tasks under conditions of no device or peroneal nerve stimulator. (30) Eleven subjects with MS, dorsiflexion weakness, and prior usage of an ankle-foot orthosis were evaluated on the timed 25-foot walk component of the MS Functional Composite and the Floor, Carpet, Up and Go, Obstacle, and Stair components of the Modified Emory Function Ambulation Profile. Performance on Stair and Obstacle components was enhanced in the stimulator condition versus no device ( $p=0.05$  and  $p=0.09$ , respectively), and there were no significant differences between no device and stimulator conditions on other measures. The authors concluded that “the neuroprosthetic effect of the peroneal nerve stimulator is modest relative to no device in the performance of specific functional tasks of ambulation in MS gait. A longitudinal, controlled trial is needed to show effectiveness.”

The study by Stein et al previously described also assessed the orthotic and therapeutic effects of NMES in 32 patients with progressive foot drop (31 MS and 1 familial spastic paresis). (27) With the stimulator on compared with off (orthotic effect), walking speed improved by 2% for a figure-8 test and 4% for a 10-meter test. With the stimulator off (therapeutic effect), walking speed at 3 months had improved by 9% for a figure-8 test and 5% for a 10-meter test when compared with baseline. The combined improvement in walking speed over the 3 months was 13% for the figure 8 (0.61 vs 0.53 m/s) and 13% for the 10-meter test (0.88 vs 0.78 m/s – both respectively). The 20 subjects (63%) who returned for testing at 11 months did not show continued improvement when compared with 3-month test results, with a combined (orthotic and therapeutic) improvement of 13% on the figure 8 (0.62 vs 0.55 m/s) and 10% on the 10-meter test (0.86 vs 0.78 m/s – both respectively) compared with baseline. The PCI was not significantly improved (0.73 vs 0.78 b/m, respectively). Subjects with nonprogressive foot drop used the device for an average 85% of days, 9.2 hours per day, and walked about 2 km/day.

### Cerebral Palsy

Cauraugh et al conducted a 2010 meta-analysis of 17 studies on NMES and gait in children with cerebral palsy. (31) Fourteen of the studies used a pretest-post-test, within-subjects design. A total of 238 participants had NMES. Included were studies on acute NMES, functional NMES and therapeutic NMES (continuous subthreshold stimulation). Five of the studies examined functional NMES, and 1 of these studies examined percutaneous NMES. There were 3 outcome measures for impairment; range of motion, torque/movement, and strength/force. There were 6 different outcome measures for activity limitations; gross motor functions, gait parameters, hopping on one foot, 6-minute walk, Leg Ability Index, and Gillette gait index. Moderate effect sizes were found for impairment (0.616) and activity limitations (0.635). The systematic review is limited by a lack of blinding in the included studies and the heterogeneity of outcome measures. The review did not describe if any of the included studies used a commercially available device.

A 2012 report examined the acceptability and effectiveness of a commercially available foot drop stimulator in 21 children who had mild gait impairments and unilateral foot drop. (32) Three children did not experience an improvement in walking and did not complete the study. Gait analysis in the remaining 18 showed improved dorsiflexion when compared with baseline. There was no significant change in other gait parameters, including walking speed. The average daily use was 5.6 hours (range,



1.5 to 9.4) over the 3 months of the study, although the participants had been instructed to use the device for at least 6 hours per day. Eighteen children (86%) chose to keep using the device after the 3-month trial period. Data from this period were collected but not reported.

In 2013, Meilahn assessed the tolerability and efficacy of a commercially available neuroprosthesis in 10 children (age, 7-12 years) with hemiparetic cerebral palsy who typically wore an ankle foot orthosis for correction of foot drop. (33) All of the children tolerated the fitting and wore the device for the first 6 weeks. The mean wear time was 8.4 hours per day in the first 3 weeks and 5.8 hours per day in the next 3 weeks. Seven children (70%) wore the device for the 3-month study period, with average use of 2.3 hours daily (range, 1.0 to 6.3 hours/day). Six children (60%) continued to use the neuroprosthesis after study completion. Gait analysis was performed, but quantitative results were not included in the report. Although it was reported that half of the subjects improved gait velocity, mean velocity was relatively unchanged with the neuroprosthesis.

**Conclusions:** Two recent within-subject studies have evaluated tolerability and efficacy of a commercially available neuroprosthesis in children with cerebral palsy. Both of the studies, which should be considered preliminary, show no improvement in walking speed with the device. In addition, daily use decreased over the course of one trial. Study in a larger number of subjects over a longer duration is needed to permit conclusions concerning the effect of the technology on health outcomes.

### **Ongoing Clinical Trials**

A search of online site [www.clinicaltrials.gov](http://www.clinicaltrials.gov) in January 2013 identified the following studies with a neuroprosthesis:

- NCT00890916 is a Phase I/II study from the Department of Veteran Affairs of the FIRSTHAND System in patients with spinal cord injury. There is an estimated enrollment of 7 patients with anticipated completion in December 2013.
- NCT00583804 will evaluate the efficacy of an implanted stimulator and sensor on hand and arm function in 50 patients with spinal cord injury. Estimated study completion date is January 2014.
- NCT01237860 is a manufacturer-sponsored Phase III study of the NESS L300 Plus System. Enrollment was estimated at 45 patients with completion in January 2011.

Also identified were a number of studies on functional NMES for treatment of patients with acute and chronic stroke conditions. These trials primarily focus on rehabilitation and strengthening.

### **Summary**

Functional neuromuscular electrical stimulation is a method being developed to restore function to patients with damaged or destroyed nerve pathways (e.g., stroke, spinal cord injury, multiple sclerosis, cerebral palsy) through use of an orthotic device with microprocessor-controlled electrical stimulation. Evidence for neuromuscular stimulation to provide functional movement in patients with spinal cord injury is limited by the small number of subjects studied to date. For chronic post-stroke foot drop, a large randomized controlled trial and crossover study of NMES versus AFO show improved satisfaction with NMES but no change in objective measures of walking. A small randomized trial examining neuromuscular stimulation for foot drop in patients with MS showed a reduction in falls and improvement in satisfaction when compared with a program of exercise, but did not demonstrate a clinically significant benefit in walking speed. The literature on NMES 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. Due to insufficient evidence for some indications, and a lack of improvement for others, functional NMES remains investigational.

### **Practice Guidelines and Position Statements**

In January 2009, the National Institute for Health and Clinical Excellence (NICE) published guidance stating that the current evidence on functional electrical stimulation for drop foot of neurologic origin appears adequate to support its use, provided that normal arrangements are in place for clinical governance, consent, and audit. (34) They noted that patient selection should involve a multidisciplinary team. NICE advises that further publication on efficacy of FES would be useful, specifically including

patient-reported outcomes, such as quality of life and ADLs, and these outcomes should be examined in different ethnic and socioeconomic groups.

### **Medicare National Coverage**

In 2002, Medicare issued a national coverage policy recommending coverage for neuromuscular electrical stimulation (NMES) for ambulation in spinal cord injury patients consistent with the FDA labeling for the Parastep device, effective April 1, 2003. (35) The Medicare decision memorandum indicates that Medicare considered the same data as those discussed here in their decision-making process. The decision memorandum notes that the available studies are flawed but concluded that the limited ambulation provided by the Parastep device supported its clinical effectiveness and thus its coverage eligibility. The inclusion and exclusion criteria outlined by Medicare are as follows:

#### **Inclusion Criteria**

- 1) persons with intact lower motor units (L1 and below);
- 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 who demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
- 4) persons who possess high motivation, commitment, and cognitive ability to use such devices for walking;
- 5) persons who can transfer independently and can demonstrate standing tolerance for at least 3 minutes;
- 6) persons who can demonstrate hand and finger function to manipulate controls;
- 7) persons with at least 6-month post-recovery spinal cord injury and restorative surgery;
- 8) persons without 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.

#### **Exclusion Criteria**

- 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.

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### **Billing Coding/Physician Documentation Information**

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<b>97116</b>	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
<b>97530</b>	Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes
<b>97760</b>	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes
<b>E0764</b>	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
<b>E0770</b>	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
<b>L5999</b>	Lower extremity prosthesis, not otherwise specified
<b>L8679</b>	Implantable neurostimulator, pulse generator, any type
<b>C1787</b>	Patient programmer, neurostimulator
<b>C1820</b>	Generator, neurostimulator (implantable), with rechargeable battery and charging system
<b>C1897</b>	Lead, neurostimulator test kit (implantable)

### **Additional Policy Key Words**

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N/A

### **Policy Implementation/Update Information**

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10/1/08	New policy titled <i>Functional Neuromuscular Stimulation</i> . The treatment of paralyzed muscles in stroke or spinal cord injury patients, multiple sclerosis or other motor function disorders is considered investigational.
7/1/00	No policy statement changes.
7/1/01	No policy statement changes.
4/1/02	No policy statement changes. Title changed to <i>Functional Neuromuscular Stimulation for the Treatment of Paralysis (FNS)</i>
4/1/03	No policy statement changes.
4/1/04	No policy statement changes.
4/1/05	Policy statement revised to read, "Functional neuromuscular stimulation as a technique to provide ambulation is considered investigational."
4/1/06	No policy statement changes.
4/1/07	No policy statement changes.
4/1/08	Policy statement revised to specifically include patients with spinal cord injury and post-stroke. This therapy remains investigational

8/1/08	Added information to the description section regarding the WalkAide.
4/1/09	No policy statement changes.
11/1/09	Additional applications (hand and foot) added to policy statement; policy title changed to "Functional neuromuscular electrical stimulation". This change is effective 10/6/09.
4/1/10	No policy statement changes.
4/1/11	Policy combined with policy 1.01.503 Neuromuscular Stimulation for Muscle Rehabilitation. Policy statement added indicating all other uses of neuromuscular stimulation as investigational.
4/1/12	No policy statement changes.
4/1/13	Policy statement revised; cerebral palsy added to investigational policy statement.
4/1/14	No policy statement changes.

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