

## Medical Policy



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### **Title: Functional Neuromuscular Stimulation (FNS) to Provide Ambulation**

*See also: Electrical Stimulation Devices for Home Use policy*

#### **Professional**

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#### **DESCRIPTION**

Functional neuromuscular stimulation attempts to replace stimuli from destroyed nerve pathways with sequential electrical stimulation of muscles to enable spinal cord injured patients to stand or walk independently or to maintain healthy muscle tone and strength. In general, only patients with lesions from T4 to T12 are considered candidates. Lesions at T1–T3 are associated with poor trunk stability, while lumbar lesions imply lower extremity nerve damage. Technologies differ in how the electrodes are placed, either implanted, placed transcutaneously, or percutaneously. To date, only one device, the Parastep® Ambulation System, has been approved by 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.” Using percutaneous stimulation, the Parastep 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). In addition, 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. Moreover, there is a finger-controlled switch that permits patient activation of the stepping.

Other devices include a reciprocating gait orthosis (RGO) with electrical stimulation. The orthosis used is a rather 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.

Functional neuromuscular stimulation is also used for gait training in post-stroke patients unable to restore normal gait with conventional physical therapy.

**POLICY**

Functional neuromuscular stimulation as a technique to provide ambulation, including ambulation in patients with spinal cord injury and post-stroke, is considered **investigational**.

**RATIONALE**

The clinical impact of Functional Neuromuscular Stimulation (FNS) rests on identification of clinically important outcomes. The primary outcome of FNS, 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, seek employment, or positively affect the patient's quality of life. Physiologic outcomes (i.e., 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 FNS 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 et al 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 13–15 patients. (2-5) In a 1997 study, Guest and colleagues reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury. (6) 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 and colleagues 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 and colleagues 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 and colleagues 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. (5) Also, Guest and colleagues reported significant improvements in physical self-concept and decreases in depression scores. (6) 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 remain compliant and committed with long-term use.

### **Summary**

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.

### **2005 Update**

Updated searches of the literature were performed in the MEDLINE database for the period of 2000 to April 2005. No published data were identified that would alter the above conclusion. Brissot and colleagues 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 and colleagues found low use of a reciprocating gait orthosis device (RGOs) with or without stimulation over an 18-month period. (9) In addition, the more recent Davis 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. (10) Therefore, the advantage of using device assistance could not be evaluated.

### **2006 Update**

An updated search of the literature was performed on the MEDLINE database for the period of April 2005 through May 2006. No published data were identified that would alter the above conclusions. Daly and colleagues compared gait component execution in 32 post-stroke patients randomized to gait training with or without FNS. (11) The authors found gait training with FNS with intramuscular electrodes significantly improved gait component execution (as measured by the Tinetti gait measure, a 12-point scale to assess gait component coordination) and knee flexion coordination over gait training without FNS. However, improvements in balance, overall limb coordination, and the 6-minute walking test were not statistically significant. In addition, final health outcomes,

such as the ability to perform activities of daily living or quality of life were not evaluated in this study.

### **2007 Update**

A search of the MEDLINE database was conducted for the period of June 2006 through September 2007. The limited published literature suggests that this procedure is at an early experimental stage in patients with spinal cord injury. For example, Forrest and colleagues reported oxygen consumption for a single subject implanted with the Case Western Reserve/Veterans Administration (CWRU/VA) standing neuroprosthesis. (12) The 12-month post-implantation assessment is part of an ongoing standardized experimental protocol funded by the New York State Department of Health Spinal Cord Injury Research Board, the U.S. Food and Drug Administration Office of Orphan Product Development, a Department of Veterans Affairs Rehabilitation and Development Merit Review, and the National Institute of Health. (13) The subject was able to stand for up to 2 hours and ambulate 8 to 15 feet in 1 minute using parallel bars. Oxygen consumption while standing was 4.7 mL/kg/min, about twice the expected energy use of a nondisabled person. At a reported ambulation speed of 2.4 to 4.5 meters per minute, the neuroprosthesis was considered to be practical only for standing, transfers, and ambulation for very short distances. Another study, which was funded by the National Center for Medical Rehabilitation Research of the National Institute for Child Health and Development, examined strategies for improving balance during functional tasks (such as reaching and manipulating objects at a counter) in 2 spinal cord injury patients using neuromuscular stimulation devices (1 with the CWRU/VA and 1 with Octostim surface electrodes). (14) It was reported that 1 of the 2 subjects attained the goal of placing at least 90% of his/her body weight on the lower extremities during standing, potentially allowing safe release of a hand for functional use. A number of publicly listed clinical trials are assessing the effectiveness of functional neuromuscular stimulation following stroke. (13) The literature indicates that functional neuromuscular neurostimulation is investigational.

### **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

#### **HCPCS**

E0764 Functional neuromuscular stimulator, transcutaneous stimulation of muscles of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program

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