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Medical Policy Manual

Topic: Functional Neuromuscular Electrical Stimulation

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IMPORTANT REMINDER

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

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Functional neuromuscular electrical 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, 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).

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, typically in healthy individuals with intact neural control.

Regulatory Status

Functional neuromuscular electrical stimulation devices have received 510(k) or pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA) for the following indications:

- Providing stimulation to trigger action potentials to allow spinal cord injured patients the ability to stand and walk.

  To date, Sigmedics' Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive PMA from the FDA. The Parastep device is approved to "enable appropriately selected skeletally mature spinal cord injured patients (level C6-T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury." Other devices include ReWalk™, by ReWalk™ Bionics research Inc., a reciprocating gait orthosis (RGO) with electrical stimulation. The orthosis used is a hip-knee-ankle-foot device linked together with a cable at the hip joint.

- Restoring upper extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadraplegia)

  Examples of these devices include: the Neurocontrol Freehand system, which received approval from the FDA through the PMA process and the Handmaster NMS I [neuromuscular stimulator], which received 510(k) clearance to provide hand active range of motion and function for patients with stroke or C5 tetraplegia.

- Improving dorsiflexion and ambulation in foot drop caused by 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. Examples of devices used for treatment of foot drop are the Innovative Neurotronics' (formerly NeuroMotion, Inc.) WalkAide®, Bioness' radio-frequency controlled NESS L300™, and Odstock Medical Limited's Foot Drop Stimulator. All have received 510(k) marketing clearance from the FDA and are intended to be used in patients with drop foot by assisting with ankle dorsiflexion during the swing phase of gait.

- Allowing patients with impaired function of the extremities to passively and actively exercise using cycle ergometry

  Cycle ergometers consist of motorized leg ergometer, optional motorized arm crank, and leg and optional arm electrical stimulation. An example of a cycle ergometer that has 510k FDA approval is the RT300 (Restorative Therapies, Inc.). Rowing devices have also been devised for exercise.

MEDICAL POLICY CRITERIA

Functional neuromuscular electrical 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** for all indications, including but not limited to the following:

I. As a technique to provide ambulation in patients with spinal cord injury

II. To restore upper or lower extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke)

III. To improve ambulation in patients with foot drop caused by congenital disorders or nerve damage (e.g., post-stroke or in those with multiple sclerosis)

IV. As a treatment of pain

SCIENTIFIC EVIDENCE

Among patients with spinal cord injury, the principal outcome associated with use of functional neuromuscular stimulation devices includes a clinically significant improvement in functional ability, such that there is an improved ability to complete activities of daily living. As a secondary outcome, positive changes in the patient's quality of life may result from improved functional ability. Physical therapy is an important component of clinical treatment of spinal cord injury. Therefore, comparisons between physical therapy with and without neuromuscular stimulation from adequately powered, blinded, randomized controlled trials (RCTs) are required to determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the standard of care.

Ambulation in Patients with Spinal Cord Injury

The literature on the effectiveness of neuromuscular stimulation devices as an aid to walking is limited to case series.

Nonrandomized Studies

Several case series have been conducted on the use of the Parastep device[1-7], a reciprocating gait orthosis device (RGOs)[8], and a surgically implanted neuroprosthesis[9] for standing and transfers as ambulatory aids. Multiple outcomes (ability to take steps, ambulate without assistance from another person, peak distance walked, increases in anthropomorphic measurements and physiologic responses, bone mineral density, self-concept, depression) were reported. Clinically significant improvements in activities of daily living were not reported, and at least one of the following limitations restricts the validity of these studies:

- Small study populations,[1-10] which limit the ability to rule out the role of chance as an explanation of study findings;
- Performing evaluations of the Parastep device immediately following initial training or in limited study period durations,[1,7-9] which limit conclusions about durability of treatment effects;
- Lack of data regarding whether patients remain compliant and committed with long-term use[1,7,8,11];
- Using the device for physical fitness, but not for ambulation,[7] which does not address clinically relevant health outcomes specified for these patient populations; and
- Reporting of physiologic outcomes (i.e., conditioning, oxygen uptake, etc.)[3,5], which are intermediate, short-term outcomes and not necessarily reflective of an improvement in functional ability.

In summary, these devices are not designed to be an alternative to a wheelchair and offer, at best, limited, short-term ambulation.[12] Final health outcomes, such as improved functional performance and

ability to perform activities of daily living, have not been reported. Without randomized comparisons, it is not known whether similar or improved results could be attained with other training methods.

Functional NMES of the Upper Extremity

The published literature on the use of functional neuromuscular electrical stimulation to improve upper extremity function secondary to spinal cord injury or stroke is limited to two RCTs and several case series.

Randomized Controlled Trials (RCT)

- In 2011, Popovic and colleagues reported on the use of the Compex Motion electric stimulator device as a supplement to conventional occupational therapy (COT) to improve voluntary grasping among 24 patients with spinal cord injury (SCI).[13] The patients were randomized to either functional electrical stimulation therapy device and COT, or COT alone for 40 hours over the course of 8 weeks. The primary outcome of interest was improvement on the Functional Independence Measure (FIM), a scale of ability to provide self-care in daily living. After 8 weeks, the functional neuromuscular electrical stimulation group had significantly higher scores on the FIM instrument and several other secondary outcomes (other scales of activities of daily living) after controlling for differences in degree of impairment between the groups. However, durability of treatment effects was not able to be compared as 18 of the original 24 subjects were lost to follow-up at 6 months.

- In 2010, Weber and colleagues reported on the use of the Bioness H200 device for use as a supplement to treatment with onabotulinumtoxinA and occupational therapy among 23 stroke patients with spasticity after stroke.[14] The primary outcome was progression in upper limb motor function, as measured by improvement in the Motor Activity Log instrument after 12 weeks of therapy. Although improvements in motor activity were seen among all patients after 6 and 12 weeks, no additional benefit was observed among patients treated with functional neuromuscular electrical stimulation versus the comparison group, potentially due to small sample size.

Nonrandomized Studies

- Kushner and colleagues assessed the efficacy of neuromuscular electrical stimulation (NMES) in addition to traditional dysphagia therapy (TDT) including progressive resistance training (PRT) compared to TDT/PRT alone during inpatient treatment of feeding tube-dependent dysphagia in patients who have had an acute stroke.[15] Ninety-two patients with an initial Functional Oral Intake Scale (FOIS) score of 3 or lower, indicating profound to severe feeding tube-dependant dysphagia, were recruited to the study. Sixty-five patients in the NMES group, received NMES with TDT/PRT, and 27 patients, the case-control group, received only TDT/PRT. Primary outcomes were FOIS scores after treatment. Authors reported significant improvements in swallowing in the NMES group compared to the TDT/PRT group ($p<0.001$). In addition, 46% of the patients in the NMES group had minimal or no swallowing restrictions after treatment compared to 26% of patients in the case-control group ($p<0.01$). This study is limited by short-term follow-up (18±3 days), which prohibits conclusions regarding the sustained benefit of NMES treatment in these patients.

- 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 US.[16-19]

- Use of the Handmaster NMS I has also been reported in patients with cervical spinal cord injuries and among[20,21] persons with chronic upper extremity paresis following stroke.[22]

Interpretation of the evidence for upper extremity neuroprostheses for patients with spinal cord injuries or post-stroke is limited by the small number of subjects[23,24] and the lack of data demonstrating its utility outside the study setting. The available evidence from cases series is insufficient to conclude that NMES improves outcomes by providing some upper extremity function. The available evidence from RCTs is suggestive that functional neuromuscular electrical stimulation provides no added benefit as a supplement to medication and occupational therapy.

Functional Neuromuscular Electrical Stimulation (NMES) for Foot Drop and Gait

The literature on the use of functional NMES for foot drop and gait among patients with chronic stroke and cerebral palsy consists mainly of case series data.

Meta-Analysis

In 2010, Cauraugh and colleagues conducted a meta-analysis of 17 studies on NMES and gait in children with cerebral palsy.[25] 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/moment, 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 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.

Randomized Controlled Trial (RCT)

- In 2009, a randomized controlled trial of functional NMES to improve walking performance in patients with multiple sclerosis (MS) was published by Barrett and colleagues.[26] 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. The primary outcome measure was walking speed over a 10-meter distance followed by secondary outcome measures of energy efficiency based on increase in heart rate during walking and walking distance in 3 minutes. Outcomes related to activities of daily living were not measured. In the NMES group, mean changes between baseline and 18-week measures were non-significant for all three 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 also 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 assignments (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. A second publication on this RCT states that it is not known how much time was spent with the devices each day and that the lack of standardized use of the NMES device is another potential confounder for these findings.[27]

- Embrey and colleagues conducted a randomized crossover trial on the efficacy of the Gait MyoElectric Stimulator for improvements in gait among 28 post-stroke patients after 3 months of use.[28] Measures of function, but not activities of daily living, were reported. Patients were a convenience sample and concurrent physical therapy was not applied.

- Knutson and colleagues conducted a randomized trial of 26 stroke patients with chronic (>6 months) foot drop comparing the effects of contralaterally controlled neuromuscular electrical stimulation (CCNMES) to cyclic neuromuscular electrical stimulation (NMES) on lower extremity impairment, functional ambulation, and gait characteristics.[29] The authors reported no significant differences between groups. In addition, the study is limited by a lack of control group with which to compare the NMES treatment group outcomes.

Nonrandomized Studies

- Three reports from Israel describe the effects of the NESS L300 for post-stroke foot drop on gait symmetry and rhythmicity, physical functioning, and participation in community life.[30-32] Outcomes related to activities of daily living, safety, or quality of life were not reported.

- In a preliminary study, Sheffler et al. compared functional ambulation tasks under conditions of no device or peroneal nerve stimulator.[33] 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. 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."

- 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.[34] 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 to 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 and data from this period was collected; however, it was 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.[35] 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.

These small studies do not demonstrate that use of a neuromuscular stimulator device provided clinically significant improvements in ambulation. A lack of treatment standardization, assessor blinding, and clinically relevant treatment outcomes limits comparisons between groups. Duration of treatment effects is also unknown. Larger longitudinal studies comparing outcomes on walking tasks and safety (fall prevention) with and without the device are still needed.

FES Cycle Ergometers and Rowing Machines

More recently there has been interest in electromyography (EMG)-triggered functional neuromuscular electrical stimulation as a therapy for patients with lower extremity paresis. Available studies on this topic include one RCT and several case series.

Randomized Controlled Trial (RCT)

In 2009, Johnston and colleagues reported on a RCT conducted on 30 children with spinal cord injury aged 5 to 13 years.[36] Children were randomly assigned by block randomization to one of three groups: cycling, with or without functional electrical stimulation (FES), or a control group receiving only electrical stimulation therapy at home 3 times a week for 6 months. Primary outcomes included improvements in oxygen uptake (VO_2), resting heart rate, forced vital capacity (FVC), and fasting lipid profile. Clinically relevant outcomes, such as those relating to activities of daily living or quality of life, were not investigated.

Nonrandomized Studies

The available studies address the intermediate physiologic effects of EMG-triggered cycling.[37-44] The studies appear to indicate a consistent impact of EMG-triggered NMES plus cycling for the following measures: (1) increased quadriceps muscle mass (validated by MRI in one study), (Calf girth did not increase significantly); (2) increased ability to perform a 30 minute work-out; (3) increased oxygen uptake during cycling exercise from 1.20 to 1.43 liters/min; (4) biopsy proven muscle atrophy normalized following one year of therapy; (5) increased pre-tibial bone mineral density following 1 year of therapy (no increase in BMD in lumbar spine or femoral neck); (6) increased tidal volume; (7) and, decreased spasticity in quadriceps muscles. The intermediate outcomes confirm what is well-established and that is that exercise is physiologically beneficial. Long term, health related outcomes and impact on quality of life for paraplegics are not measured. The studies do not indicate that FES plus cycling affect paraplegia in any way by decreasing paralysis or allowing the patient to better function independently.

It is not clear that the benefits accomplished with EMG-triggered NMES plus cycling cannot be realized through standard passive range of motion exercise. Based on the available published evidence, additional RCTs comparing this therapy to standard treatment are still required.

Clinical Practice Guidelines

In 2010, the Department of Veterans Affairs (VA), Department of Defense (DoD) and The American Heart Association/ American Stroke Association published a Clinical Practice Guideline for the Management of Stroke Rehabilitation, recommending the use of functional electrical stimulation for shoulder subluxation and as an adjunctive treatment for gait training.[45] Specifically, they stated, “FES

has been used for several years as a therapy modality for post-stroke patients, but has not been a routine standard of care. FES is a time-limited intervention, generally used during the first several weeks after the acute stroke." The guideline found that use of FES was linked to intermediate health outcomes, but that high-quality evidence did not exist linking it to primary health outcomes.

Summary

Based on the lack of published long-term objective outcomes from well-designed, well-executed randomized controlled clinical trials, conclusions cannot be reached concerning the effectiveness of functional electrical stimulation (FES) as a therapy for any indication. Therefore FES is considered investigational for all indications, including but not limited to treatment of pain and treatment of functional impairment due to nerve damage caused by trauma (e.g., spinal cord injury), stroke, congenital disorders, or neuromuscular disease (e.g., multiple sclerosis). Larger, randomized, placebo-controlled trials of longer duration are needed to evaluate the effectiveness of FES devices in improving strength, function or mobility, and minimizing pain and to determine whether FES offers any additional benefit compared with sham treatment or other standard treatments.

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CROSS REFERENCES

Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83

CODES	NUMBER	DESCRIPTION
CPT	None	
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
	E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (new code effective 1/1/09)
	E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)
	E0744	Neuromuscular stimulator for scoliosis
	E0745	Neuromuscular stimulator, electronic shock unit