Medical Policy Manual

**Topic:** Functional Neuromuscular Electrical Stimulation  
**Date of Origin:** July 2000

**Section:** Durable Medical Equipment  
**Last Reviewed Date:** December 2016

**Policy No:** 83.04  
**Effective Date:** January 1, 2017

**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 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**

Functional neuromuscular electrical stimulation is 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. 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 (no longer available), which received approval from the FDA through the PMA process and the NESS H200® (previously known as the Handmaster NMS I system), 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. 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 devices used for treatment of foot drop are the Innovative Neurotronics’ (formerly NeuroMotion, Inc.) WalkAide®, Bioness’ radio-frequency controlled NESS L300™, MyGait (Otto Bock HealthCare), 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.[1-10] NMES devices are not designed to be an alternative to a wheelchair and offer, at best, limited, short-term ambulation.[11] 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 Neuromuscular Electrical Stimulation (NMES) of the Upper Extremity**

**Systematic Review**

A systematic review by Gu et al. evaluated electrical stimulation for hemiplegic shoulder function.[12] This review included 15 RCTs, and the results of a meta-analysis showed that FES improved shoulder subluxation, but only if it was applied early after stroke. There were no significant effects seen for pain, upper arm motor function, daily function, or quality of life measures.

**Randomized Controlled Trials (RCTs)**

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 et al. 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. 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.

Some recent RCTs have compared different types of NES. For example, a study published in 2016 compared the effects of contralaterally controlled functional electrical stimulation (CCFES) with cyclic neuromuscular electrical stimulation (cNMES) in 80 stroke patients with chronic upper extremity hemiparesis. Treatment was given over 12 weeks, and consisted of 10 sessions per week of either CCFES- or cNMES-assisted hand opening exercise at home and 20 sessions of functional practice in the laboratory. For the CCFES group, the task practice was stimulation assisted. Outcomes assessed were the change in Box and Block Test, upper extremity Fugl-Meyer and Arm Motor Abilities Test. At six months follow-up, the CCFES group showed greater improvement in the Box and Block test, but there were no significant difference in the other outcomes. There were no non-stimulation control groups in this study, which limits the conclusions that can be drawn.

In addition, a small pilot study evaluated task-oriented electromyography (EMG)-triggered electrical stimulation for shoulder subluxation in participants with subacute hemiparetic stroke. There were 10 patients randomized to the EMG-triggered stimulation group and 10 to the control group that received cyclic FES. The treatments were given five times a week for four week, and all patients additionally received four weeks of conventional physical therapy. There were significant improvements in shoulder subluxation, muscle activation, and pain (by Visual Analogue Scale) in the EMG-triggered stimulation group compared to the control FES group, but no differences in the Fugl-Meyer assessment.

In a larger, single-blind RCT that compared EMG-triggered, cyclic, and sensory electrical stimulation, 122 patients with upper-limb hemiplegia from stroke were randomized to receive one of these treatments twice every weekday for eight weeks. After 6 months, there were no differences between the groups in any of the outcomes, which included the Fugl-Meyer assessment, FMA Wrist and Hand, and modified Arm Motor Ability test.

Conclusion

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 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 NMES for Foot Drop and Gait
The literature on the use of functional NMES for foot drop and gait among patients for various indications, including: chronic stroke, cerebral palsy, and multiple sclerosis; consists primarily of case series data[20-25], several RCTs, and one meta-analysis.

**Systematic Reviews**

A systematic review published in 2016 compared FES with ankle foot orthoses (AFO) for the treatment of foot drop after stroke.[26] Seven published studies were included, which represented five different trials with a total of 815 participants. The included trials were judged to be of medium-methodologic quality by the reviewers. Meta-analyses of study data showed similar improvements for both groups in 10m walking speed, functional exercise capacity, perceived mobility, and timed up-and-go. The authors concluded that both treatment modalities appeared to be equally effective and stated that “While combining data from different types of AFO/FES does not allow a detailed look at the possible different effects of each individual sub-type, assuming the prescription of devices within each trial was provided on the basis of clinical judgement and complies with current guidelines, this allows for a clinically relevant comparison.” Another systematic review evaluated peroneal stimulation for foot drop in stroke patients, with similar conclusions.[27]

In 2010, Cauraugh and colleagues conducted a meta-analysis of 17 studies on NMES and gait in children with cerebral palsy.[28] 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 three outcome measures for impairment; range of motion, torque/moment, and strength/force. There were six 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 Trials (RCTs)**

In 2016, a small pilot RCT was published that assessed the effects of NMES in combination with mirror therapy in stroke survivors with hemiplegia.[29] There were 14 patients randomized to NMES plus mirror therapy and physical therapy, and 13 patients randomized to the control treatment of physical therapy alone. Balance, muscle strength and tone, and gait were evaluated at baseline and after four weeks of treatment. The authors reported significant improvements in strength, balance, and walking tests following the intervention.

Another RCT compared locomotor training fast walking plus FES to locomotor training at self-selected or fast speeds without FES in 50 poststroke participants.[30] While fast walking plus FES resulted in larger reductions in energy expenditure with walking than non-FES locomotor training, there were no differences between groups in the 6-minute walk test.

In 2014 Bethoux et al. conducted a large multicenter industry-affiliated RCT to compare a foot-drop stimulator (WalkAide) with an ankle-foot orthosis (AFO) in 495 Medicare-eligible individuals who were at least 6 months poststroke.[31] A total of 399 individuals completed the 6-month study. Primary outcome measures were the 10-Meter Walk Test (10MWT), a composite measure of daily function, and
device-related serious adverse events (AEs). There were 7 secondary outcome measures that assessed function and quality of life. Intention-to-treat analysis found that both groups improved walking performance over the 6 months of the study, and the NMES device was noninferior to the AFO on the primary outcome measures. Only the WalkAide group showed significant improvements from baseline to 6 months on several secondary outcome measures, but there were no significant between-group differences for any of the primary outcomes.

In 2013, Taylor and colleagues conducted a small RCT to evaluate FES and physiotherapy exercise for dropped foot and hip instability in 28 patients with secondary progressive multiple sclerosis. Authors reported that both physiotherapy and FES improved mobility; however, these findings should be interpreted with caution due to the small sample size and cross-over study design whereby all patients received FES.

In 2013, Kluding and colleagues conducted an industry-sponsored single-blind multicenter trial that randomized 197 patients to 30 weeks of a foot drop stimulator (NESS L300) or a conventional ankle-foot orthosis (AFO). 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.

In 2013, a small multicenter within-subject crossover trial was published that compared the WalkAide footdrop stimulator versus conventional AFO. Patients who had a stroke within the previous 12 months and residual footdrop but no prior experience with an orthotic device were randomly assigned to WalkAide followed by AFO (6 weeks each, n=38), AFO followed by WalkAide (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. 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 10MWT), while the WalkAide tended to have a greater therapeutic effect. The orthotic effect on PCI was significantly higher with an AFO than the WalkAide. Users felt equally safe with the 2 devices. Seventy percent preferred to keep the WalkAide after the 12-week study.

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. 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.

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. Measures of function, but not activities of daily living, were reported. Patients were a convenience sample and concurrent physical therapy was not applied.

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. 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.[38]

Conclusion

These 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[39] and several case series.[40-47]

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.[39] 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 (VO2), 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.

Conclusion

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

Department of Veterans Affairs (VA), Department of Defense (DoD) and The American Heart Association/ American Stroke Association

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.[48] 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

There is not enough research to show if or how well neuromuscular electrical stimulation (NMES) works to treat people with stroke, spinal cord injury, or other conditions. Therefore, functional NMES is considered investigational for all indications, including but not limited to treatment of spinal cord injury, stroke, congenital disorders, or neuromuscular disease.

REFERENCES


**CROSS REFERENCES**

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

<table>
<thead>
<tr>
<th>CODES</th>
<th>NUMBER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E0764</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>E0770</td>
<td>Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified</td>
</tr>
<tr>
<td>CODES</td>
<td>NUMBER</td>
<td>DESCRIPTION</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td>E0731</td>
<td>Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)</td>
</tr>
<tr>
<td></td>
<td>E0744</td>
<td>Neuromuscular stimulator for scoliosis</td>
</tr>
<tr>
<td></td>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
</tr>
</tbody>
</table>