

# Protocol

## Functional Neuromuscular Electrical Stimulation

(80301)

<b>Medical Benefit</b>		<b>Effective Date:</b> 08/01/20	<b>Next Review Date:</b> 05/21
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 03/07, 05/08, 05/09, 01/10, 01/11, 01/12, 01/13, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20	

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

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

Populations	Interventions	Comparators	Outcomes
Individuals: • With loss of hand and upper-extremity function due to spinal cord injury or stroke	Interventions of interest are: • Functional neuromuscular electrical stimulation	Comparators of interest are: • Standard of care	Relevant outcomes include: • Functional outcomes • Quality of life
Individuals: • With chronic footdrop	Interventions of interest are: • Functional neuromuscular electrical stimulation	Comparators of interest are: • Standard of care • Ankle-foot orthosis	Relevant outcomes include: • Functional outcomes • Quality of life
Individuals: • With spinal cord injury at segments T4 to T12	Interventions of interest are: • Functional neuromuscular electrical stimulation	Comparators of interest are: • Standard of care	Relevant outcomes include: • Functional outcomes • Quality of life
Individuals: • With spinal cord injury	Interventions of interest are: • Functional electrical stimulation exercise equipment	Comparators of interest are: • Standard of care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

### DESCRIPTION

Functional electrical stimulation (FES) involves the use of an orthotic device or exercise equipment with micro-processor-controlled electrical muscular stimulation. These devices are being developed to restore function and improve health in patients with damaged or destroyed nerve pathways (e.g., spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy).

### SUMMARY OF EVIDENCE

For individuals who have loss of hand and upper-extremity function due to SCI or stroke who receive FES, the evidence includes case series. The relevant outcomes are functional outcomes and quality of life (QOL). Evidence

on FES for the upper limb in patients with SCI or stroke includes a few small case series. Interpretation of the evidence is limited by the low number of patients studied and lack of data demonstrating the utility of FES outside the investigational setting. It is uncertain whether FES can restore some upper-extremity function or improve the QOL. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic footdrop who receive FES, the evidence includes randomized controlled trials and a systematic review. The relevant outcomes are functional outcomes and QOL. For chronic post-stroke footdrop, two randomized controlled trials comparing FES with a standard ankle-foot orthosis showed improved patient satisfaction with FES but no significant differences between groups in objective measures like walking. A randomized controlled trial with 53 subjects examining neuromuscular stimulation for footdrop in patients with multiple sclerosis showed a reduction in falls and improved patient satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be corroborated. The literature on FES in children with cerebral palsy includes a systematic review of small studies with within-subject designs. Further study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SCI at segments T4 to T12 who receive FES, the evidence includes case series. The relevant outcomes are functional outcomes and QOL life. No controlled trials were identified on FES for standing and walking in patients with SCI. However, case series are considered adequate for this condition, because there is no chance for unaided ambulation in this population with SCI at this level. Some studies have reported improvements in intermediate outcomes, but improvements in health outcomes (e.g., ability to perform activities of daily living, QOL) have not been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SCI who receive FES exercise equipment, the evidence includes prospective within-subject comparisons. The relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on FES exercise equipment consists primarily of within-subject, pre- to post-treatment comparisons. Evidence was identified on two commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is a limited amount of evidence on the RT300 series. None of the studies showed an improvement in health benefits and one analysis of use for 314 individuals over 20,000 activity sessions with a Restorative Therapeutics device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of six days per week, but caloric expenditure remained low. Compliance was shown in one study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function. A limitation of these studies is that they all appear to have been conducted in supervised in research centers. No studies were identified on long-term home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

## POLICY

Neuromuscular stimulation is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations:

- To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or poststroke); or
- To improve ambulation in patients with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., poststroke or in those with multiple sclerosis); or
- As a technique to provide ambulation in patients with spinal cord injury.

Functional electrical stimulation devices for exercise in patients with spinal cord injury are considered **investigational**.

### POLICY GUIDELINES

This policy does not refer to commercially available exercycles that use electrical muscle stimulation technology as a means of physical therapy and exercise for patients with spinal cord injury. 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.

### MEDICARE ADVANTAGE

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

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

1. Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);
2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
3. Persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
4. Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;
5. Persons that can transfer independently and can demonstrate independent standing tolerance for at least three minutes;
6. Persons that can demonstrate hand and finger function to manipulate controls;
7. Persons with at least six-month post recovery spinal cord injury and restorative surgery;
8. Persons 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.

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

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

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

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

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

### **MEDICARE ADVANTAGE POLICY GUIDELINES**

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

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

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

### **BACKGROUND**

#### **FUNCTIONAL ELECTRICAL STIMULATION**

FES is an approach to rehabilitation that applies low-level electrical current to stimulate functional movements in muscles affected by nerve damage. It focuses on the restoration of useful movements, like standing, stepping, pedaling for exercise, reaching, or grasping.

FES 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, cycle, or grasp. Functional neuromuscular stimulators are closed-loop systems that provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities (e.g., walking). These systems are contrasted with open-loop systems, which are used for simple tasks (e.g., muscle strengthening alone); healthy individuals with intact neural control benefit the most from this technology.

Applications, described in more detail in the Rationale section, include upper-extremity grasping function after spinal cord injury and stroke, lifting the front of the foot during ambulation in individuals with footdrop, ambula-

tion and exercise for patients with spinal cord injury. Some devices are used primarily for rehabilitation rather than home use. This protocol focuses on devices intended for home use.

## REGULATORY STATUS

A variety of FES devices have been cleared by the U.S. Food and Drug Administration (FDA) and are available for home use. Table 1 provides examples of devices designed to improve hand and foot function as well as cycle ergometers for home exercise. The date of the FDA clearance is for the first 510(k) clearance identified for a marketed device. Many devices have additional FDA clearances as the technology evolved, each in turn listing the most recent device as the predicate.

Table 1. Functional Electrical Stimulation Devices Cleared by the FDA

Device	Manufacturer	Device Type	Clearance	Date	Product Code
Freehand®	No longer manufactured	Hand stimulator		1997	
NESS H200® (previously Handmaster)	Bioness	Hand stimulator	K022776	2001	GZC
MyndMove System	MyndTec	Hand stimulator	K170564	2017	GZI/IPF
ReGrasp	Rehabtronics	Hand stimulator	K153163	2016	GZI/IPF
WalkAide® System	Innovative Neurotronics (formerly NeuroMotion)	Foot drop stimulator	K052329	2005	GZI
ODFS® (Odstock Dropped Foot Stimulator)	Odstock Medical	Foot drop stimulator	K050991	2005	GZI
ODFS® Pace XL	Odstock Medical	Foot drop stimulator	K171396	2018	GZI/IPF
L300 Go	Bioness	Foot drop stimulator	K190285	2019	GZI/IPF
Foot Drop System	SHENZHEN XFT Medical	Foot drop stimulator	K162718	2017	GZI
MyGait® Stimulation System	Otto Bock HealthCare	Foot drop stimulator	K141812	2015	GZI
ERGYS (TTI Rehabilitation Gym)	Therapeutic Alliances	Leg cycle ergometer	K841112	1984	IPF
RT300	Restorative Therapies, Inc (RTI)	Cycle ergometer	K050036	2005	GZI
Myocycle Home	Myolyn	Cycle ergometer	K170132	2017	GZI
StimMaster Orion	Electrologic (no longer in business)				

FDA: Food and Drug Administration.

To date, the Parastep® Ambulation System (Sigmedics, Northfield, IL) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval 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.”<sup>1</sup> FDA product code: MKD.

## RELATED PROTOCOLS

Microprocessor-Controlled Prostheses for the Lower Limb

Myoelectric Prosthetic and Orthotic Components for the Upper Limb

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary

Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

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

## REFERENCES

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

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