Medical Coverage Policy | Functional Neuromuscular Electrical Stimulation

EFFECTIVE DATE: 07/01/2024
POLICY LAST REVIEWED: 04/16|2025

OVERVIEW

Functional electrical stimulation (FES) involves the use of an orthotic device or exercise equipment with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function and improve health in individuals with damaged or destroyed nerve pathways (eg, spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy). The objective of this evidence review is to determine whether use of functional neuromuscular electrical stimulation improves the net health outcome in individuals with functional disabilities related to spinal cord injury or stroke or with chronic foot drop. Some devices are used primarily for rehabilitation rather than home use. This policy focuses on devices intended for home use.

This policy applies to Commercial Products only. For Medicare Advantage Plans, refer to the Related Policies section.

MEDICAL CRITERIA

Commercial Products
Not applicable

PRIOR AUTHORIZATION

Commercial Products
Not applicable

POLICY STATEMENT

Commercial Products
Neuromuscular stimulation as a technique to restore function following nerve damage or nerve injury is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome. This includes its use in the following situations:

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

Functional electrical stimulation devices for exercise in individuals with spinal cord injury is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable durable medical equipment or not medically necessary/not covered benefits/coverage.

BACKGROUND

Functional Electrical Stimulation
There are 2 broad categories of neuromuscular electrical stimulation (NMES) devices: one targets muscle atrophy during rest, and the other enhances functional activity in neurologically impaired patients. These devices use electrical impulses to activate weak or paralyzed muscles in precise sequences. The technology often referred to as functional electrical stimulation (FES) is used for both upper and lower extremity

rehabilitation, with a specific focus on enhancing mobility and independence. 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.

Functional electrical stimulation devices consist of an orthotic and a microprocessor-based electronic stimulator with 1 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 (eg, walking). These systems are contrasted with open-loop systems, which are used for simple tasks (eg, 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 (SCI) and stroke; lifting the front of the foot during ambulation in individuals with foot drop; and ambulation and exercise for patients with SCI. Functional electrical stimulation devices vary in size and design based on the treatment area and goals. These devices typically include a neuromuscular electrical stimulator unit, wires or wireless connectors, and electrodes, which may attach to the skin, be inserted under the skin, or be inputted through surgery to target specific muscles or nerves. Some devices are used primarily for rehabilitation rather than home use. This evidence review 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.

Device	Manufacturer	Device Type
NESS H200® (previously Handmaster)	Bioness	Hand stimulator
MyndMove System	MyndTec	Hand stimulator
ReGrasp	Rehabtronics	Hand stimulator
WalkAide® System	Innovative Neurotronics (formerly NeuroMotion)	Foot drop stimulator
ODFS® (Odstock Dropped Foot Stimulator)	Odstock Medical	Foot drop stimulator
ODFS® Pace XL	Odstock Medical	Foot drop stimulator
L300 Go	Bioness	Foot drop stimulator
L100 Go	Bioness	Foot drop stimulator
Foot Drop System	SHENZHEN XFT Medical	Foot drop stimulator
Nerve And Muscle Stimulator	SHENZHEN XFT Medical	Foot drop stimulator
MyGait® Stimulation System	Otto Bock HealthCare	Foot drop stimulator
MStim Drop Model LGT-233	Guangzhou Longest Science & Technology	Foot drop stimulator
ERGYS (TTI Rehabilitation Gym)	Therapeutic Alliances	Leg cycle ergometer
RT300	Restorative Therapies, Inc (RTI)	Cycle ergometer

Myocycle Home	Myolyn	Cycle ergometer
Cionic Neural Sleeve NS-100	Cionic	Foot drop stimulator
EvoWalk 1.0	Evolution Devices Inc	Foot drop stimulator
Neuvotion NeuStim NN-01	Neuvotion Inc	Hand stimulator

To date, the Parastep® Ambulation System (Sigmedics) 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 to 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."

Upper-Extremity Function After Spinal Cord Injury and Stroke

One application of functional electrical stimulation (FES) is to restore upper-extremity functions such as grasp-release, forearm pronation, and elbow extension in individuals with stroke, or C5 and C6 tetraplegia (quadriplegia). The relevant population of interest is individuals with loss of hand and upper-extremity function due to spinal cord injury (SCI) or stroke. NeuroControl Corp. developed the Freehand System, an implantable upper-extremity neuroprosthesis, to improve the ability to grasp, hold, and release objects for individuals with tetraplegia due to C5 or C6 SCI. NeuroControl is no longer in business, but FES centers in the United States and United Kingdom provide maintenance for implanted devices.

The NESS H200 (previously known as the Handmaster NMS I system) is an upper-extremity device that uses a forearm splint and surface electrodes. The device, controlled by a user-activated button, is intended to provide hand function (fine finger grasping, larger palmar grasping) for individuals with C5 tetraplegia or stroke. Other hand stimulators that have been cleared for marketing in the United States include ReGrasp (Rehabtronics) and MyndMove (MyndTec).

The evidence on FES for the upper limbs in patients with SCI or stroke includes a limited number of small case series and an RCT. Interpretation of the evidence for upper-extremity neuroprostheses for these populations is limited by the small number of patients studied and lack of data demonstrating its utility outside the investigational (study) setting.

Functional Electrical Stimulation for Chronic Foot Drop

Other FES devices have been developed to provide FES for 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. Functional electrical stimulation of the peroneal nerve has been suggested for these individuals as an aid in raising the toes during the swing phase of ambulation. With 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 such devices used for treatment of foot drop are:

- WalkAide by Innovative Neurotronics (formerly NeuroMotion)
- L300 Go by Bioness
- MyGait by Otto Bock
- ODFS (Odstock Dropped Foot Stimulator) and ODFS Pace XL by Odstock.

For chronic poststroke foot drop, a meta-analysis and 2 RCTs comparing FES with a standard AFO showed no significant differences between groups in objective measures such as walking, but the RCTs indicated some improved patient satisfaction with FES. A longitudinal cohort study assessed patients' ability to avoid obstacles while walking on a treadmill using FES versus AFO. Although the FES group averaged a 4.7% higher rate of avoidance, the individual results between devices ranged widely. One RCT with 53 subjects examining neuromuscular stimulation for foot drop 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. Another RCT showed that at 12 months, both FES and AFO had improved walking speed. Another RCT showed that at 12 months, both FES and AFO had improved walking speed, but the difference in improvement between the 2 devices was not significant. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be confirmed in a larger number of patients. The literature on FES in children with cerebral palsy includes 3 systematic reviews of small studies with within-subject designs. All included studies only measure short-term results; it is unclear what the long-term effects of FES may be in this population. Further study in a larger number of subjects for a longer duration of study is needed.

Ambulation in Patients With Spinal Cord Injury

Another application of FES is to provide individuals with SCI the ability to stand and walk. 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 electric impulses are controlled by a computer microchip attached to the individual's belt, which synchronizes and distributes the signals. In addition, there is a finger-controlled switch that permits individual activation of the stepping.

Other devices include a reciprocating gait orthosis 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 donning and doffing the device. The purpose of FES for ambulation in individuals who have SCI is to provide a treatment option that is an alternative to or an improvement on existing therapies. Generally, only individuals with SCI with lesions from T4 to T12 are considered candidates for ambulation systems. Lesions at T1 to T3 are associated with poor trunk stability, while lumbar lesions imply lower-extremity nerve damage.

To date, the Parastep Ambulation System (Sigmedics) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval 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 to 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.

The evidence on functional FES for standing and walking in patients with SCI consists of case series. Case series are considered adequate for this condition because there is no chance for ambulation in patients with SCI between segments T4 to T12. As stated by various authors, these systems are not designed as alternatives to a wheelchair and offer, at best, limited, short-term ambulation. Some studies have reported improvements in intermediate outcomes, but improvement in health outcomes (eg, ability to perform ADLs) have not been demonstrated. Finally, evaluations of these devices were performed immediately after initial training or during limited study period durations. There are no data in which patients remained compliant and committed with long-term use.

Functional Electrical Stimulation Exercise Equipment for Spinal Cord Injuries

The U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion recommends 2 days per week of muscle strengthening for both healthy adults and adults with disabilities, and at least 150 minutes to 300 minutes (5 hours) of moderate-intensity aerobic activity per week or 75 minutes to 150 minutes of vigorous aerobic activity. In patients with SCI, inactivity due to injury or barriers to exercise can lead to multiple degenerative changes that include muscle atrophy, bone mass loss and osteoporosis, and reduction in cardiopulmonary function. Other adverse effects of inactivity that are common with SCI include muscle spasms and weight gain, which may predispose individuals to metabolic syndrome, type 2 diabetes, and their associated health problems.

Functional electrical stimulation cycle ergometers are available in rehabilitation facilities. An ergometer is a device that measures work performed by exercising. When the term "ergometer" is used in the context of

FES, it refers to exercise equipment that measures both position and speed and stimulates muscles in a prescribed sequence to provide coordinated movement (eg, cycling) of the paralyzed limb. The devices can provide increasing resistance as work capacity increases, and reduce stimulation when fatigue is detected (eg, a speed of cycling below 35 rpm). Some models of FES cycle ergometers have been designed for home exercise in individuals with SCI and are the focus of this evidence review.

The proposed benefit of FES exercise equipment is to counteract the health consequences of paralyzed limbs and include:

- Prevention of muscle atrophy
- Reduction of muscle spasms
- Improvement of circulation
- Improvement in range of motion
- Improvement in cardiopulmonary function
- Reduction in pressure sore frequency
- Improvements in bowel and bladder function
- Decreased incidence of urinary tract infections

The majority of home FES devices are cycle ergometers for the lower limbs of individuals with lower extremity paresis, although some devices may also include upper arm exercise. All of the devices have evolved over the past 3 decades. Some have internet capability and can be programmed remotely.

- The REGYS and ERGYS series ergometers are manufactured by Therapeutic Alliances. These devices are the largest, include a computer console, and require transfer to an integrated seat. The ERGYS3 is a fourth generation device; earlier models continue to be utilized.
- There are several models of the RT300 by Restorative Therapies, Inc (RTI). The RT300-S includes both leg and arm cycles. This device is used with the patient's own wheelchair and does not require a transfer.
- The Myocycle Home by Myolyn is designed for home use and is the simplest of the cycle ergometers.
- The StimMaster Orion was manufactured by Electrologic. Electrologic ceased business operations in 2005.

The evidence on FES exercise equipment consists primarily of within-subject, pretreatment to posttreatment comparisons. Evidence was identified on 2 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 within-subject studies showed an improvement in health benefits; however, improvement in body fat with RT300 was found in a small group of patients when FES high intensity interval cycling was added to nutrition counseling compared to nutritional counseling alone. One analysis of use for 314 individuals over 20,000 activity sessions with a Restorative Therapies 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 6 days per week, but caloric expenditure remained low. Compliance was shown in 1 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; however, a small comparative study found arm cycling to improve exercise energy expenditure and cardiorespiratory fitness to a greater extent than FES leg cycling. A limitation of these studies is that they all appear to have been conducted in supervised 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.

For individuals who have loss of hand and upper-extremity function due to spinal cord injury (SCI) or stroke who receive functional electrical stimulation (FES), the evidence includes a few small case series and a randomized controlled trial (RCT). Relevant outcomes are functional outcomes and quality of life. 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 quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic foot drop who receive FES, the evidence includes RCTs, meta-analyses, and a longitudinal cohort study. Relevant outcomes are functional outcomes and quality of life. For chronic poststroke foot drop, 2 RCTs comparing FES with a standard ankle-foot orthosis (AFO) showed improved patient satisfaction with FES but no significant differences between groups in objective measures such as walking. Another RCT found no significant differences between use versus no use of FES on walking outcomes. Similarly, one meta-analysis found no difference between AFO and FES in walking speed, and another meta-analysis found no difference between FES and conventional treatments. The cohort study assessed patients' ability to avoid obstacles while walking on a treadmill using FES versus AFO. Although the FES group averaged a 4.7% higher rate of avoidance, the individual results between devices ranged widely. One RCT with 53 subjects examining neuromuscular stimulation for foot drop 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. Another RCT showed that at 12 months, both FES and AFO had improved walking speed, but the difference in improvement between the 2 devices was not significant. Another study found FES (combined with postural correction) and neuroproprioceptive facilitation and inhibition physiotherapy did not differ in walking speed or balance immediately or 2 months after program end. 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 3 systematic reviews of small studies with within-subject designs. All included studies only measure short-term results; it is unclear what the long-term effects of FES may be in this population. Further study is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI at segments T4 to T12 who receive FES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of 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 (eg, ability to perform activities of daily living [ADL], quality of life) have not been demonstrated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI who receive FES exercise equipment, the evidence includes prospective comparisons. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on FES exercise equipment consists primarily of within-subject, pretreatment to posttreatment comparisons. Evidence was identified on 2 commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is limited evidence on the RT300 series. None of the within-subject studies showed an improvement in health benefits; however, improvement in body fat with RT300 was found in a small group of patients when FES high intensity interval cycling was added to nutrition counseling compared to nutritional counseling alone. One analysis of use for 314 individuals over 20,000 activity sessions with a Restorative Therapies 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 6 days per week, but caloric expenditure remained low. Compliance was shown in 1 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; however, a small comparative study found arm cycling to improve exercise energy expenditure and cardiorespiratory fitness to a greater extent than FES leg cycling. A limitation of these studies is that they all appear to have been conducted in supervised 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 that the technology results in an improvement in the net health outcome.

CODING

The following HCPCS Code(s) are not medically necessary for Commercial Products:

E0764 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

E0770 Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

RELATED POLICIES

Prior Authorization via Web-Based Tool for Durable Medical Equipment (DME)
Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations

PUBLISHED

Provider Update, June 2025
Provider Update, May 2024
Provider Update, July 2023
Provider Update, July 2022
Provider Update, July 2021

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