



FEP Medical Policy Manual

FEP 8.03.01 Functional Neuromuscular Electrical Stimulation

Effective Policy Date: July 1, 2022

Original Policy Date: December 2011

Related Policies:

- 1.03.04 - Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities
- 1.04.04 - Myoelectric Prosthetic and Orthotic Components for the Upper Limb
- 1.04.05 - Microprocessor-Controlled Prostheses for the Lower Limb

Functional Neuromuscular Electrical Stimulation

Description

Description

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 patients with damaged or destroyed nerve pathways (eg, spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy).

OBJECTIVE

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.

POLICY STATEMENT

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 (eg, spinal cord injury or poststroke); or
- To improve ambulation in patients 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 patients with spinal cord injury.

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 | GZI |
| 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 |

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|--------------------------------|--|----------------------|---------|------|---------|
| L100 Go | Bioness | Foot drop stimulator | K200262 | 2020 | GZI/IPF |
| Foot Drop System | SHENZHEN XFT Medical | Foot drop stimulator | K162718 | 2017 | GZI |
| Nerve And Muscle Stimulator | SHENZHEN XFT Medical | Foot drop stimulator | K193276 | 2020 | GZI |
| MyGait Stimulation System | Otto Bock HealthCare | Foot drop stimulator | K141812 | 2015 | GZI |
| MStim Drop Model LGT-233 | Guangzhou Longest Science & Technology | Foot drop stimulator | K202110 | 2021 | GZI/IPF |
| 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: U.S. Food and Drug Administration.

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-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."¹ FDA product code: MKD.

RATIONALE

Summary of Evidence

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. 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 randomized controlled trials (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 a systematic review of small studies with within-subject designs. 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 [ADLs], 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in "Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2009, NICE published guidance stating that the evidence on functional electrical stimulation for foot drop of neurologic origin appeared adequate to support its use.⁴⁴ The Institute noted that patient selection should involve a multidisciplinary team. The Institute advised that further publication on the efficacy of functional electrical stimulation would be useful, specifically including patient-reported outcomes (eg, quality of life, activities of daily living [ADL]) and these outcomes should be examined in different ethnic and socioeconomic groups.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare (2002; updated in 2006) issued a national coverage policy recommending coverage for neuromuscular electrical stimulation for ambulation in spinal cord injury patients consistent with the U.S. Food and Drug Administration (FDA) labeling for the Parastep device.^{1,45} The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in its decision-making process. The decision memorandum noted that the available studies were flawed but concluded that the limited ambulation provided by the Parastep device supported its clinical effectiveness and thus its coverage eligibility. The inclusion criteria outlined by Medicare are as follows:

- "Persons with intact lower motor units (L1 and below)...;
- 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;
- Persons who demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
- Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

- Persons that can transfer independently and can demonstrate standing tolerance for at least 3 minutes;
- Persons that can demonstrate hand and finger function to manipulate controls;
- Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
- Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
- Persons that have demonstrated a willingness to use the device long-term."

The exclusion criteria are as follows:

- "Persons with cardiac pacemakers;
- Severe scoliosis or severe osteoporosis;
- Skin disease or cancer at area of stimulation;
- Irreversible contracture; or
- Autonomic dysreflexia."

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|----------------|----------------|---|
| December 2011 | New policy | |
| June 2012 | Replace policy | Policy statement changed to read not medically necessary. Related policies added. References 25, 27 added |
| June 2013 | Replace policy | Policy updated with literature review; references 11-12 and 29- 31 added; congenital disorders, cerebral palsy added to policy statement. |
| June 2014 | Replace policy | Policy was updated with literature review, adding references 20 and 21. No changes were made to the policy statement. Policy Summary revised with no change to intent of policy. |
| June 2015 | Replace policy | Policy was updated with literature review, adding references 20 and 21. Policy statement is unchanged |
| December 2017 | Replace policy | Policy updated with literature review through June 22, 2017; reference 1 added. Policy statement unchanged. |
| June 2018 | Replace policy | Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged except "as a technique to provide ambulation in patients with spinal cord injury" changed from investigational to not medically necessary due to FDA PMA status of the Parastep. |
| September 2019 | Replace policy | Policy updated with literature review through March 8, 2019. Review of functional electrical stimulation exercise equipment added to policy; this is considered investigational. |
| September 2020 | Replace policy | Policy updated with literature review through March 9, 2020; references added. Policy statements unchanged. |
| June 2021 | Replace policy | Policy updated with literature review through January 23, 2021; references added. Policy statements unchanged. |
| July 2022 | Replace policy | Policy updated with literature review through January 21, 2022; references added. Policy statements unchanged. |

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