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# MEDICAL POLICY – 8.03.01

# Functional Neuromuscular Electrical Stimulation

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| BCBSA Ref. Policy: | 8.03.01 |
| Effective Date: | June 1, 2024 |
| Last Revised: | May 13, 2024 |
| Replaces: | N/A |

RELATED MEDICAL POLICIES:

| | |
|---|---|
| 1.01.507 | Electrical Stimulation Devices |
| 1.03.04 | Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities |
| 1.04.502 | Myoelectric Prosthetic and Orthotic Components for the Upper Limb |
| 1.04.503 | Microprocessor-Controlled Prostheses for the Lower Limb |
| 7.01.69 | Sacral Nerve Neuromodulation/Stimulation |

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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## Introduction

To move a muscle, the brain sends an electrical signal. The signal travels along the nerve to the muscle fibers. When the muscle fibers receive the signal, they move. Instead of the electrical signals coming from the brain, functional neuromuscular electrical stimulation sends electricity to the muscles through an external power source. The signals arise from a microprocessor and flow to electrodes that are placed on the skin with a patch or implanted. The electrical signals stimulate the targeted nerves to create muscle contractions. This technique has been proposed as a way to try to bring back muscle function after illness, injury, or surgery. It has also been proposed to strengthen muscles that haven't been used for some time. There is not enough evidence in the medical studies published to date to show how well this proposed treatment works. For this reason, it's considered investigational (unproven).

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

| Procedure | Investigational |
|---|---|
| **Neuromuscular stimulation** | **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:**<br>• As a technique to provide ambulation in individuals with spinal cord injury (SCI)<br>• To provide upper extremity function in individuals with nerve damage (e.g., SCI or post-stroke)<br>• To improve ambulation in individuals with foot-drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., post-stroke or in those with multiple sclerosis)<br><br>**Functional electrical stimulation devices for exercise in individuals with spinal cord injury is considered investigational (see Benefit Application).** |

## Coding

| Code | Description |
|---|---|
| **HCPCS** | |
| 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 (such as the ParaStep - an ambulation aid for patients with spinal cord injury) |
| E0770 | Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (such as stimulators used in patients with footdrop) |

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

## Benefit Application

Functional electrical stimulation (FES) devices including but not limited to the following are considered home exercise equipment: ERGYS (leg cycle ergometer, REGYS (leg cycle RT200 Elliptical, RT300 RES cycle ergometer (also referred to as FES bicycle), StimMaster Galaxy (FES exercise bike) or the RT600 Step and Stand Rehabilitation Therapy System for stationary exercise.

The Company considers FES devices to be home exercise equipment. Most contract plans exclude coverage of exercise equipment for use in the home. Please refer to the member's contract language for details.

# Evidence Review

## 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 individuals with damaged or destroyed nerve pathways (e.g., spinal cord injury (SCI), stroke, multiple sclerosis, cerebral palsy).

## 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 individuals 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 include upper-extremity grasping function after SCI and stroke, lifting the front of the foot during ambulation in individuals with footdrop, ambulation, and exercise for individuals with SCI. Some devices are used primarily for rehabilitation rather than home use. This policy focuses on devices intended for home use.

## 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 a few small case series and a randomized controlled trial (RCT). The relevant outcomes are functional outcomes and quality of life. Interpretation of the evidence is limited by the low number of individuals 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 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 footdrop who receive FES, the evidence includes RCTs, meta-analyses, and a longitudinal cohort study. The relevant outcomes are functional outcomes and quality of life. For chronic poststroke footdrop, two RCTs comparing FES with a standard ankle-foot orthosis (AFO) showed improved individual satisfaction with FES, but no significant difference 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 individuals' 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 individuals with multiple sclerosis showed a reduction in falls and improved individual 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 two 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 two 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. The relevant outcomes are functional outcomes and quality of life. No controlled trials were identified on FES for standing and walking in individuals 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 improvement in health outcomes (e.g., 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. The relevant outcomes are symptoms, functional outcomes, and quality of life. 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 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 individuals 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 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; 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.

## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

## Table 1. Summary of Key Trials

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| **Ongoing** | | | |
| NCT03949387 | Functional Electrical Stimulation Cycling for Managing Mobility Disability in People With Multiple Sclerosis | 40 | Dec 2024 |
| NCT03410498 | The Orthotic Effect of Functional Electrical Stimulation to Treat Foot Drop in People With MS Under Walking Conditions Simulating Those in Daily Life | 20 | Dec 2024 |
| NCT04945395 | The Effect of Using Functional Electric Stimulation for the Recovery of Dorsiflexion During Rehabilitation of Gait Function, in the Subacute Phase After Stroke- a Randomized Controlled Exploratory Study | 20 | Feb 2024 |
| NCT03495986 | Spinal Cord Injury Exercise and Nutrition Conceptual Engagement (SCIENCE) | 60 | May 2024 |
| NCT00583804 | Implanted Myoelectric Control for Restoration of Hand Function in Spinal Cord Injury | 10 (actual) | Jan 2026 |
| **Unpublished** | | | |
| NCT00890916 | Hand Function for Tetraplegia Using a Wireless Neuroprosthesis | 10 | May 2021 |
| NCT03385005 | Evaluating Neuromuscular Stimulation for Restoring Hand Movements | 8 | Jun 2023 |

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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 FES for footdrop of neurologic origin appeared adequate to support its use.[47] 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 (e.g., quality of life, activities of daily living) and these outcomes should be examined in different ethnic and socioeconomic groups.

## Medicare National Coverage

Medicare (2002 updated in 2006) issued a national coverage policy recommending coverage for neuromuscular electrical stimulation (NMES) for ambulation in SCI patients consistent with the US Food and Drug Administration (FDA) labeling for the Parastep device.[1,48] The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in their 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:

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

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

The exclusion criteria are as follows:

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

## Regulatory Status

A variety of FES devices have been cleared by the US Food and Drug Administration (FDA) and are available for home use. **Table 2** 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 2. Functional Electrical Stimulation Devices Cleared by the FDA

| Device | Manufacturer | Device Type | Clearance | Date | Product Code |
|---|---|---|---|---|---|
| NESS H200 (previously Handmaster) | Bioness | Hand stimulator | K022776 | 2001 | GZI |

| Device | Manufacturer | Device Type | Clearance | Date | Product Code |
|---|---|---|---|---|---|
| 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 |
| 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 |
| Cionic Neural Sleeve NS-100 | Cionic | Foot drop stimulator | K221823 | 2022 | GZI/IPF |
| EvoWalk 1.0 | Evolution Devices Inc | Foot drop stimulator | K230997 | 2023 | GZI |

FDA: US 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 SCI."[1]

FDA product code: MKD.

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## History

| Date | Comments |
|---|---|
| 01/97 | Add to Therapy Section - New Policy |
| 06/27/00 | Replace Policy - Policy revised to focus on ambulation. |
| 05/13/03 | Replace Policy - Literature review update; added to Rationale/Source section; No change in policy statement. |
| 06/08/04 | Replace Policy - Policy updated; no change in policy statement. |
| 08/09/05 | Replace Policy - Policy reviewed with literature search; no new clinical trials found. Policy statement unchanged. |
| 02/06/06 | Codes updated - No other changes. |
| 06/23/06 | Update Scope and Disclaimer - No other changes. |
| 12/11/07 | Replace Policy - Policy updated with literature review; policy statement clarified to include: "ambulation in patients with spinal cord injury and post-stroke" as investigational. References added. |
| 06/09/09 | Replace Policy - Policy updated with literature search. Policy statements modified to add a second policy statement that use of these devices in post-stroke patients is considered investigational. References added. |
| 10/13/09 | Replace Policy - Policy extensively updated with literature search. Additional applications added to policy statement (hand and foot). Title updated to Functional neuromuscular electrical stimulation. References updated. |
| 03/08/11 | Replace Policy - Policy updated with literature review; references added and reordered. Policy statement remains unchanged. |
| 04/25/12 | Replace policy. Policy updated with literature review through December 2011; reference 25 added; policy statement unchanged. |
| 10/09/12 | Update Coding Section – ICD-10 codes are now effective 10/01/2014. |
| 04/08/13 | Replace policy. Policy updated with literature review through January 16, 2013; references 11-12 and 29-31 added; cerebral palsy added to investigational policy statement. |
| 06/14/13 | Update Related Policies. Change title for 7.01.69 to "Sacral Nerve Neuromodulation/Stimulation". |

| Date | Comments |
|---|---|
| 09/09/13 | Clarification note added. This policy does not apply to specialized exercise equipment, such as the RT 300 Exercycle, that is used in the rehabilitation setting under the supervision of a physical therapist or other rehab specialist. Please refer to medical policy 8.03.502. |
| 12/19/13 | Update Related Policies. Remove 1.01.19 as it was archived. |
| 05/05/14 | Annual Review. Policy updated with literature review January 7, 2014. References 20 and 21 added; others renumbered/removed. Policy statement unchanged. All codes removed from policy with the exception of HCPCS codes; these are the only code utilized for adjudication. |
| 06/27/14 | Update Related Policies. Change title to 1.01.17. |
| 04/24/15 | Annual Review. Policy updated with literature review through January 16, 2015; references 20 and 22 added; policy statement unchanged. Clarification notes in policy statements retained. |
| 08/28/15 | Update Related Policies. Remove 1.01.17 and 8.01.39 as they were archived. |
| 11/19/15 | Update related policies. Remove 7.01.522. |
| 07/01/16 | Annual Review, approved June 14, 2016. Literature review. Added reference 36. No change to policy statement. Clarification added on FES devices. |
| 11/01/16 | Interim Update, approved October 11, 2016. Policy updated with literature review through July 11, 2016; references added/removed/renumbered. Policy statement unchanged. |
| 10/01/17 | Annual Review, approved September 21, 2017. Policy moved into new format. Policy updated with literature review through June 22, 2017; reference 1 added. Policy statement unchanged. *This policy varies slightly from the BCBSA Reference Policy. |
| 05/01/18 | Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged. |
| 08/01/19 | Annual Review, approved July 9, 2019. Policy updated with literature review through March 2019. Review of functional electrical stimulation exercise equipment added to policy; this is considered investigational. |
| 08/01/20 | Annual Review, approved July 2, 2020. Policy updated with literature review through March, 2020; references added. Policy statements unchanged. |
| 06/01/21 | Annual Review, approved May 4, 2021. Policy updated with literature review through January 23, 2021; references added. Policy statements unchanged. |
| 06/01/22 | Annual Review, approved May 9, 2022. Policy updated with literature review through January 21, 2022; references added. Policy statements unchanged. |
| 06/01/23 | Annual Review, approved May 5, 2023. Policy updated with literature review through February 6, 2023; references added. Minor editorial refinements to policy statements; |

| Date | Comments |
|---|---|
| | intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. |
| 06/01/24 | Annual Review, approved May 13, 2024. Policy updated with literature review through January 22, 2024; no references added. Policy statements unchanged. |



**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.