Functional Neuromuscular Electrical Stimulation

Policy # 00042
Original Effective Date: 05/12/2003
Current Effective Date: 08/09/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers neuromuscular stimulation as a technique to restore function following nerve damage or nerve injury to be **investigational.***

This includes its use in the following situations:

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

Based on review of available data, the Company considers functional electrical stimulation devices for exercise in patients with spinal cord injury to be **investigational.***

Background/Overview

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 (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 and stroke, lifting the front of the foot during ambulation in individuals with foot drop, ambulation and exercise for patients with spinal cord injury. Some devices are used primarily for rehabilitation rather than home use. This evidence review focuses on devices intended for home use.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A variety of FES devices have been cleared by the U.S. 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
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
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." FDA product code: MKD.

Rationale/Source

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).

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 foot drop 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 foot drop, 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 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. 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 (eg, 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 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 studies showed an improvement in health benefits and 1 analysis of use for 314 individuals over 20000 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.

Supplemental Information

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

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.

In 2009, the National Institute for Health and Care Excellence (NICE) published guidance stating that the evidence on functional electrical stimulation for foot drop of neurologic origin appeared adequate to support its use. 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) 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. FDA labeling for the Parastep device. 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."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT00890916	Hand Function for Tetraplegia Using a Wireless Neuroprosthesis	11	Dec 2022
NCT02602639	Functional Electrical Stimulation with Rowing as Exercise after Spinal Cord Injury (FES)	6	Sep 2022
NCT03385005	Evaluating Neuromuscular Stimulation for Restoring Hand Movements	15	Jun 2021
NCT03495986	Spinal Cord Injury Exercise and Nutrition Conceptual Engagement (SCIENCE)	40	Jul 2022
NCT03440632	Functional Electrical Stimulation during walking cerebral palsy	25	Aug 2021

NCT00583804	Implanted Myoelectric Control for Restoration of Hand Function in Spinal Cord Injury	10	Jan 2026
Unpublished			
NCT03810963	Electrically Induced Cycling and Nutritional Counseling for Counteracting Obesity After SCI	15	May 2019 (updated 10/04/19)

NCT: national clinical trial.

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Policy History

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04/25/2003	Medical Policy Committee review
05/12/2003	Managed Care Advisory Council approval
05/03/2005	Medical Director review
05/17/2005	Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
05/23/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/01/2007	Medical Director review
08/15/2007	Medical Policy Committee approval Coverage eligibility unchanged. Rationale /Source updated.
08/06/2009	Medical Policy Committee approval.
08/26/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2010	Medical Policy Committee approval.

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08/18/2010	Medical Policy Implementation Committee approval. Title changed to Functional Neuromuscular Electrical Stimulation. Additional investigational statements added.
10/01/2010	Coding revision only
08/04/2011	Medical Policy Committee approval.
08/17/2011	Medical Policy Implementation Committee approval. No change to coverage.
08/02/2012	Medical Policy Committee review
08/15/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2013	Medical Policy Committee review
08/21/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2014	Medical Policy Committee review
08/20/2014	Medical Policy Implementation Committee approval. Cerebral palsy added to investigational statement.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Coverage changes with the review of functional electrical stimulation exercise equipment added to policy; this is considered investigational.

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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Code Type	Code
CPT	95971, 95972
HCPCS	C1883, E0764, E0770
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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