BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 8.03.01 Functional Neuromuscular Electrical Stimulation

Effective Policy Date: October 1, 2019

Original Policy Date: December 2011

Related Policies:

1.03.04 Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

1.04.04 Myoelectric Prosthesis Components for the Upper Limb
1.04.05 Microprocessor-Controlled Prostheses for the Lower Limb

Functional Neuromuscular Electrical Stimulation

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 footdrop.

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

Neuromuscular stimulation is considered **not medically necessary** 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**.

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

The Parastep® Ambulation System (Sigmedics, Northfield, IL) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from 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.

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.

RATIONALE

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 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 FEScan 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 RCTs and a systematic review. The relevant outcomes are functional outcomes and QOL. For chronic poststroke footdrop, two RCTs comparing FES with a standard AFO showed improved patient satisfaction with FES but no significant differences between groups in objective measures like walking. An RCT with 53 subjects examining neuromuscular stimulation for footdrop in patients with MS 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. 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

Practice Guidelines and Position Statements

The National Institute for Health and Care Excellence (2009) published guidance stating that the evidence on functional electrical stimulation for footdrop of neurologic origin appeared adequate to support its use.[30] 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 Food and Drug Administration labeling for the Parastep device.[36,] 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:

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 that possess high motivation, commitment and cognitive ability to use such devices for walking;
5. Persons that can transfer independently and can demonstrate standing tolerance for at least 3 minutes;
6. Persons that can demonstrate hand and finger function to manipulate controls;
7. Persons with at least 6-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 that 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; or
5. 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- 31added; congenital disorders, cerebral palsy added to policy statement.

Date	Action	Description
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.