MEDICAL POLICY

POLICY TITLE	NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION
POLICY NUMBER	MP-6.051

Effective Date:	9/1/2023

I. POLICY

Neuromuscular Electrical Stimulation (NMES)

Neuromuscular electrical stimulation (NMES) to treat muscle atrophy may be considered **medically necessary** when the following criteria are met:

- The nerve supply to the muscle is intact (including brain, spinal cord, and peripheral nerves); **and**
- The patient has any of the following conditions:
  - Previous casting or splinting of a limb; **or**
  - Contractures due to scarring from burns; **or**
  - Recent hip replacement surgery (until rehabilitation therapy begins); **or**
  - Previous major knee surgery (when there is failure to respond to rehabilitation therapy.)

Functional Neuromuscular Electrical Stimulation

To support independent ambulation, Functional Neuromuscular Electrical Stimulation for spinal cord injury (e.g. Parastep Ambulation System) may be considered **medically necessary** for patients with diagnosis of paraplegia and meet **ALL** of the following criteria**:**

- Intact lower motor units (L1 and below) (both muscle and peripheral nerve); **and**
- 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; **and**
- Demonstrate brisk muscle contraction to NMES; **and**
- Possess high motivation, commitment and cognitive ability to use such devices for walking; **and**
- Transfer independently and can demonstrate standing tolerance for at least 3 minutes; **and**
- Demonstrate hand and finger function to manipulate controls or have an attendant available that can manipulate the controls; **and**
- At least 6-month post recovery spinal cord injury and restorative surgery; **and**
- Without severe, untreated hip and knee degenerative disease that prohibits them from the joint range of motion necessary for ambulation and no history of long bone fracture secondary to osteoporosis; **and**

- Demonstrated a willingness to use the device long-term; **and**
- Have completed a training program which consists of physical medicine sessions with the device, (Parastep® Ambulation System) (typically over a period of three (3) months).

Functional neuromuscular electrical stimulation for spinal cord injury (e.g. Parastep Ambulation System) is contraindicated in the following instances:

- cardiac pacemakers
- severe scoliosis or severe osteoporosis
- skin disease or cancer at the area of stimulation
- irreversible contractures
- autonomic dysreflexia

All other types of Functional Neuromuscular Electrical Stimulation devices and uses, including but not limited to, foot drop, stroke, multiple sclerosis or cerebral palsy, are considered **investigational**.

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure for the above indications.

Cross-references:
MP-6.020 Transcutaneous Electrical Nerve Stimulation
MP-6.045 Sympathetic Therapy for the Treatment of Pain
MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP-6.047 Interferential Current Stimulation
MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
MP-6.049 H-Wave Electrical Stimulation
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO- Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Neuromuscular electrical stimulation (NMES)

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NMES involves the use of a device that transmits electrical impulse to the skin over selected muscle groups by way of electrodes. There are two categories of NMES. One is used to treat muscle atrophy and stimulates the muscle when the individual is in a resting state. The other, also known as functional electrical stimulation (FES), is used to enhance functional activity of neurologically impaired and spinal cord injured (SCI) patients.

Functional electrical stimulation

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).

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 footdrop, and 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.

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.

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Table 1. 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	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
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

FDA: 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.

IV. RATIONALE

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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). 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 outcomes.

For individuals who have chronic footdrop 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 footdrop, 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 (e.g., ability to perform activities of daily living, quality of life) have not been demonstrated.

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 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 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 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.

V. DEFINITIONS

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510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
A4560	E0745	E0764						

Investigational; therefore not covered:

Procedure Codes								
E0770								

ICD-10-CM Diagnosis Code	Description
G82.20	Paraplegia, unspecified
G82.21	Paraplegia, complete

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ICD-10-CM Diagnosis Code	Description
G82.22	Paraplegia, incomplete
M62.50	Muscle wasting and atrophy, not elsewhere classified, unspecified site
M62.511	Muscle wasting and atrophy, not elsewhere classified, right shoulder
M62.512	Muscle wasting and atrophy, not elsewhere classified, left shoulder
M62.519	Muscle wasting and atrophy, not elsewhere classified, unspecified shoulder
M62.521	Muscle wasting and atrophy, not elsewhere classified, right upper arm
M62.522	Muscle wasting and atrophy, not elsewhere classified, left upper arm
M62.529	Muscle wasting and atrophy, not elsewhere classified, unspecified upper arm
M62.531	Muscle wasting and atrophy, not elsewhere classified, right forearm
M62.532	Muscle wasting and atrophy, not elsewhere classified, left forearm
M62.539	Muscle wasting and atrophy, not elsewhere classified, unspecified forearm
M62.541	Muscle wasting and atrophy, not elsewhere classified, right hand
M62.542	Muscle wasting and atrophy, not elsewhere classified, left hand
M62.549	Muscle wasting and atrophy, not elsewhere classified, unspecified hand
M62.551	Muscle wasting and atrophy, not elsewhere classified, right thigh
M62.552	Muscle wasting and atrophy, not elsewhere classified, left thigh
M62.559	Muscle wasting and atrophy, not elsewhere classified, unspecified thigh
M62.561	Muscle wasting and atrophy, not elsewhere classified, right lower leg
M62.562	Muscle wasting and atrophy, not elsewhere classified, left lower leg
M62.569	Muscle wasting and atrophy, not elsewhere classified, unspecified lower leg
M62.571	Muscle wasting and atrophy, not elsewhere classified, right ankle and foot
M62.572	Muscle wasting and atrophy, not elsewhere classified, left ankle and foot
M62.579	Muscle wasting and atrophy, not elsewhere classified, unspecified ankle and foot
M62.58	Muscle wasting and atrophy, not elsewhere classified, other site
M62.59	Muscle wasting and atrophy, not elsewhere classified, multiple sites
M62.5A0	Muscle wasting and atrophy, not elsewhere classified, back, cervical
M62.5A1	Muscle wasting and atrophy, not elsewhere classified, back, thoracic
M62.5A2	Muscle wasting and atrophy, not elsewhere classified, back, lumbosacral
M62.5A9	Muscle wasting and atrophy, not elsewhere classified, back, unspecified level
Z47.1	Aftercare following joint replacement surgery

IX. REFERENCES

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X. POLICY HISTORY

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MP 6.051	**6/24/20 Consensus review.** Policy statement unchanged. Product variation, benefit variation, disclaimer, coding, and references updated.

POLICY TITLE	NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION
POLICY NUMBER	MP-6.051

	6/18/21 Consensus review. Policy statement unchanged. Revised Summary of evidence and Table 1. Removed diagnosis codes M62.52 and M62.56. References added.
	06/24/2022 Minor review. Functional Neuromuscular Electrical Stimulation (FNES) changed from E/I to medically necessary with criteria for spinal cord injury. Contraindications for FNES also listed. Added ICD10 codes G82.20, G82.21 and G82.22. FEP language updated. Rationale revised. References added.
	8/15/2022. Administrative update. ICD10 codes M62.5A0, M62.5A1, M62.5A2 and M62.5A3 added to policy; effective 10/1/2022.
	3/16/2023. Administrative update New Code A4560 added Effective 4/1/23.
	05/19/2023 Consensus review. No change to policy statement. Product Variation statement, Background and Rationale updated. References added.

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