MEDICAL POLICY



MEDICAL POLICY DETAILS			
Medical Policy Title	Functional Electrical Stimulation (FES) and Neuromuscular Electrical Stimulation		
	(NMES)		
Policy Number	1.01.48		
Category	Technology Assessment		
Original Effective Date	05/18/05		
Committee Approval	06/15/06, 05/17/07, 06/19/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 04/18/13, 05/22/14,		
Date	04/16/15, 04/21/16, 04/20/17, 04/19/18, 06/20/19, 07/16/20, 07/15/21, 07/21/22, 08/17/23,		
	08/22/24		
Current Effective Date	08/22/24		
Archived Date	N/A		
Archive Review Date	N/A		
Product Disclaimer	• Services are contract dependent; if a product excludes coverage for a service, it is not		
	covered, and medical policy criteria do not apply.		
	• If a commercial product (including an Essential Plan or Child Health Plus product),		
	medical policy criteria apply to the benefit.		
	• If a Medicaid product covers a specific service, and there are no New York State		
	Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.		
	• If a Medicare product (including Medicare HMO-Dual Special Needs Program		
	(DSNP) product) covers a specific service, and there is no national or local Medicare		
	coverage decision for the service, medical policy criteria apply to the benefit.		
	• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a		
	specific service, please refer to the Medicaid Product coverage line.		

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, neuromuscular electrical stimulation (NMES) for treatment of disuse atrophy, lymphedema, or tissue damage (e.g., chronic wounds) has not been proven to be effective and, therefore, is considered **not medically necessary**.
- II. Based upon our criteria and assessment of the peer-reviewed literature, NMES for treatment of motor disorders; including but not limited to, cerebral palsy, spina bifida, and some non-progressive myopathies has not been proven to be effective and, therefore, is considered **not medically necessary**.
- III. Based upon our criteria and assessment of the peer-reviewed literature, NMES for treatment of dysphagia has not been proven to be effective and, therefore, is considered **not medically necessary**.
- IV. Based upon our criteria and assessment of the peer-reviewed literature, functional electrical stimulation (FES) is considered **not medically necessary** for all indications; including ambulation in patients with spinal cord injury, stroke rehabilitation, and gait training.

Refer to Corporate Medical Policy #1.01.01 Transcutaneous and Percutaneous Nerve Stimulation as a Treatment for Pain and Other Conditions

Refer to Corporate Medical Policy #1.01.07 Oral Appliance for the Treatment of Obstructive Sleep Apnea

DESCRIPTION

Neuromuscular electrical stimulation (NMES) is a form of treatment that uses a device that transmits an electrical impulse to activate muscle groups by way of electrodes. The stimulator device is classified as durable medical equipment. NMES

Policy Number: 1.01.48

Page: 2 of 5

can be referred to as functional electrical stimulation (FES), functional neuromuscular stimulation (FNMS), or electromyography (EMG) triggered neuromuscular stimulation.

FES involves the use of an orthotic device or exercise equipment with microprocessor controlled electrical muscular stimulation. FES 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). It attempts to replace stimuli from destroyed nerve pathways with computer-controlled sequential electrical stimulation of muscles through surface or implanted electrodes. The goal is to enable patients with spinal cord injury (SCI) or stroke to function independently or at least maintain muscle tone and strength. Surface or percutaneous devices for upper extremity FES (e.g., H200 Wireless Hand Rehabilitation System) combine a wrist/hand orthosis with integrated surface electrodes to activate muscles of the paralyzed forearm and hand. Upper extremity surface FES devices may be most effective when used soon after spinal cord injury, during the acute phase of rehabilitation.

Threshold electrical stimulation (TES) uses surface electrodes to stimulate the muscle when the patient is in a resting state. It is intended to increase muscle strength and joint mobility, leading to improved voluntary motor function.

Parastep I is a surface FES device intended to allow patients with lower extremity paralysis to stand and walk short distances. The WalkAide system is another FES device that improves the walking ability of people suffering from Foot Drop. WalkAide uses sensor technology to analyze the movement of the leg and foot, sending electrical signals to the peroneal nerve which activates the muscles to raise the foot at the appropriate time during the step cycle. Implanted FES devices (e.g., the Freehand System) devices incorporate surgically implanted stimulation electrodes, an implanted stimulator, and an external power supply. A shoulder position sensor mounted on the chest and shoulder translates small shoulder movements into a control signal. Use of these devices requires intensive and lengthy training by rehabilitation specialists.

The MicroVas stimulator is purported to increase blood flow and tissue oxygenation, promote lymphatic drainage, and induce involuntary exercise. However, it has not been proven for this purpose.

VitalStim Therapy is a type of neuromuscular electrical stimulation in which a small current is passed through external electrodes placed on the neck to stimulate inactive or atrophied swallowing muscles. With repeated therapy, throat muscles are reported to be re-trained, and the patient is progresses to an optimum level of swallow function.

Functional Electrical Stimulation Devices Cleared by the FDA (not an all-inclusive list)

Device	Manufacturer	Device Type	Date
NESS H200 (previously Handmaster)	Bioness	Hand Stimulator	2001
MyndMove System	MyndTec	Hand Stimulator	2017
WalkAide System	Innovative Neurotronics (formerly NeuroMotion)	Foot drop stimulator	2005
L100 Go	Bioness	Foot drop stimulator	2020
EvoWalk 1.0	Evolution Devices Inc	Foot drop stimulator	2023
ERGYS (TTI Rehabilitation Gym)	Therapeutic Alliances	Leg cycle ergometer	1984
Myocycle Home	Myolyn	Cycle ergometer	2017

RATIONALE

A number of neuromuscular stimulators for therapeutic electrical stimulation have received U.S. Food and Drug Administration (FDA) approval. There is insufficient evidence in the peer reviewed literature to conclude that neuromuscular stimulation is as beneficial as other forms of treatment for disuse atrophy, scoliosis, stroke rehabilitation,

Policy Number: 1.01.48

Page: 3 of 5

lymphedema, chronic wounds, or prevention of complications related to musculoskeletal or circulatory impairment after spinal cord injury. Randomized, controlled trials do not demonstrate that neuromuscular stimulation improves motor function in children with cerebral palsy.

Several functional electrical stimulation devices have received FDA approval, including_the Parastep I, the NeuroControl Freehand System, the Ness H200 Hand Rehabilitation System, the Ness L300 Foot Drop System, G. Estim FES, and the WalkAide System. There is insufficient data to demonstrate that FES results in improved net health outcomes. Data is insufficient regarding whether patients remain compliant and committed with long-term use of the devices.

No published studies of the MicroVas device were identified. Micro Vas therapy has been around since the late 1980s. It was originally used to treat hypothermia in Navy Seals who experienced the negative effects of extreme temperatures. Over time, Micro Vas therapy evolved into a treatment for neuropathy and other painful conditions, especially those that affect the extremities.

To date, there have been very few studies of surface electrical stimulation to the neck for swallowing that support the efficacy of VitalStim. These studies have small sample size and report mixed results. There is insufficient evidence in the peer reviewed literature to conclude that electrical stimulation is effective in the treatment of dysphagia.

Stimulators have not been studied in pregnant women or patients with seizures and balance disorders.

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN)

CPT Codes

Code	Description
64580	Open (Incision) for implantation of neurostimulator electrode array; neuromuscular
64585	Revision or removal of peripheral neurostimulator electrode array
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)

Copyright © 2024 American Medical Association, Chicago, IL

HCPCS Codes

Code	Description
E0744 (NMN)	Neuromuscular stimulator for scoliosis
E0745 (NMN)	Neuromuscular stimulator, electronic shock unit
E0764 (NMN)	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
E0769 (NMN)	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
E0770 (NMN)	Functional neuromuscular stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

Policy Number: 1.01.48

Page: 4 of 5

Code	Description
G0281 (NMN)	Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care
G0282 (NMN)	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
G0283 (NMN)	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

ICD10 Codes

Code	Description
Various	

REFERENCES

*Bethoux F, et al. The effects of peroneal nerve functional electrical stimulation versus ankle-foot orthosis in patients with chronic stroke: a randomized control trial. <u>Neurorehabil Neural Repair</u> 2014 Sep;28(7):688-97.

*Bosch PR, et al. Review of therapeutic electrical stimulation for dorsiflexion assist and orthotic substitution from the American congress of rehabilitation medicine stroke movement interventions subcommittee. <u>Arch Phys Med Rehabil</u> 2014 Feb;95(2):390-6.

Chen HC, et al. Effectiveness of neuromuscular electrical stimulation in improving mobility in children with cerebral palsy: A systematic review and meta-analysis of randomized controlled trials. Clin Rehabil 2023 Jan;37(1):3-16.

Dantas et al. Gait training with functional electrical stimulation improves mobility in people post-stroke. <u>International</u> Journal of Environmental Research and Public Health 2023 May; 20(9):5728.

*Evereart DG., et al. Effect of a foot-drop stimulator and ankle-foot orthosis on walking performance after stroke: a multi-centered randomized controlled trial. Neurorehabil Neural Repair 2013;27(7):579-91.

Gilligan C, et al. Three-year durability of restorative neurostimulation effectiveness in patient with chronic low back pain and multifidus muscle dysfunction. Neuromodulation 2023 Jan;26(1):98-108.

Glavind Holmsted Kristensen M et al. Neuromuscular electrical stimulation improves activities of daily living post stroke: a systematic review and meta-analysis. <u>Archives of Rehabilitation Research and Clinical Translation</u> 2022 Mar;4(1): 100167-100182.

*Hascakova-Bartov M., et al. Neuromuscular electrical stimulation of completely paralyzed abdominal muscles in spinal cord-injured patients: a pilot study. Spinal Cord 2008;46:445–50.

Juckes FM, et al. A cohort study of functional electrical stimulation in people with multiple sclerosis demonstrating improvements in quality of life and cost-effectiveness. <u>Clin Rehabil</u> 2019 Jul;33(7):1163-1170.

*Kluding PM, et al. Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. <u>Stroke</u> 2013 Jun;44(6):1660-9.

Marcus S, et al. Neuromuscular electrical stimulation for treatment of dysphagia in infants and young children with neurological impairment: a prospective pilot study. BMJ Paediatrics Open 2019 Jan;3(1) e000382.

Marquez-Chin C and Popovic MR. Functional electrical stimulation therapy for restoration of motor function after spinal cord injury and stroke: a review. Biomed Eng Online 2020;19:34.

Policy Number: 1.01.48

Page: **5** of **5**

*O'Dell MW, et al. Response and prediction of improvement in gait speed from functional electrical stimulation in persons with poststroke drop foot. <u>PM&R</u> 2014 Jul;6(7):587-601.

*Pereira S, et al. Functional electrical stimulation for improving gait in persons with chronic stroke. <u>Top Stroke Rehabil</u> 2012 Nov-Dec;19(6):491-8.

Renfrew L, et al. The clinical- and cost-effectiveness of functional electrical stimulation and ankle-foot orthoses for foot drop in Multiple Sclerosis: a multicentre randomized trial. Clin Rehabil 2019 Jul;33(7):1150-1162.

*Sommerfelt K, et al. Therapeutic electrical stimulation in cerebral palsy: a randomized, controlled, crossover trial. <u>Dev Med Child Neur</u> 2001;43:609-613.

*Stein RB, et al. Progressive and nonprogressive neurological disorders long-term therapeutic and orthotic effects of a foot drop stimulator on walking. <u>Neurorehabil Neural Repair</u> 2010;24;152-167.

*Key Article

KEY WORDS

Functional Electrical Stimulator, Neuromuscular Stimulator, Therapeutic Electrical Stimulator.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD#160.12) for Neuromuscular Electrical Stimulation (NMES). Please refer to the following NCD website for Medicare Members:

[http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=175&ncdver=2&bc=BAABAAAAAAA&] accessed 07/10/24.