MEDICAL POLICY

Excellus

SUBJECT: NEUROMUSCULAR ELECTRICAL STIMULATION (NMES)	EFFECTIVE DATE: 05/18/05 REVISED DATE: 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, 04/16/15, 04/21/16, 4/20/17, 04/19/18
POLICY NUMBER: 1.01.48 CATEGORY: Technology Assessment	PAGE: 1 OF: 4

- ***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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare 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***

POLICY STATEMENT:

I. Based upon our criteria and review 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 is considered **not medically necessary.**

II. Based upon our criteria and review of the peer-reviewed literature, NMES has not been proven to be effective and is considered **not medically necessary** for treatment of *motor disorders*; including but not limited to, cerebral palsy, spina bifida, and some non-progressive myopathies.

III. Based upon our criteria and review of the peer-reviewed literature, NMES has not been proven to be effective and is considered **not medically necessary** for treatment of dysphagia.

III. Based upon our criteria and review of the peer-reviewed literature, functional electrical stimulation (FES) is more costly than an Ankle-Foot Orthosis and is at least as likely to produce equivalent therapeutic results; therefore 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 Electrical Stimulation (TENS) and H-Wave Stimulation

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Neuromuscular electrical stimulation (NMES) 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.

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. NMES used to enhance functional activity of neurologically impaired patients is also referred to as functional stimulation (FES or FNMS) or EMG-triggered neuromuscular stimulation. 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. Handmaster™) 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. Parastep I® is a surface FES device intended to allow patients with lower extremity paralysis to stand and walk short distances. WalkAide Systems 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 (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 but has not been proven to increase blood flow and tissue oxygenation, promote lymphatic drainage, and induce involuntary exercise.

VitalStim® Therapy is a type of neuromuscular electrical stimulation where 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.

RATIONALE:

A number of neuromuscular stimulators for therapeutic electrical stimulation have received 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, 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.

Five functional electrical stimulation devices - the Parastep I®, NeuroControl Freehand® System, the Ness Handmaster™, the Ness L300™ and the WalkAide® System have received FDA approval. There is insufficient data to demonstrate that FES results in improved net health outcomes. There are no data regarding whether patients remain compliant and committed with long-term use.

No published studies of the MicroVas device were identified.

To date, there are 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: Number Description

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:	64580	Incision for implantation of neurostimulator electrodes; neuromuscular

HCPCS:	E0744 **(NMN)**	Neuromuscular stimulator for scoliosis
	E0745 **(NMN)**	Neuromuscular stimulator, electronic shock unit
	E0764 (**NMN)**	Functional neuromuscular stimulator, transcutaneous stimulation of muscles 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, no otherwise specified

ICD10: Various

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* 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) 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=BAABAAAAAAAA&