FEP 8.03.01 Functional Neuromuscular Electrical Stimulation

Effective Date: July 15, 2018

Related Policies:
1.03.04 Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities
1.04.04 Myoelectric Prosthetic Components for the Upper Limb
1.04.05 Microprocessor Controlled Prosthesis for the Lower Limb

Functional Neuromuscular Electrical Stimulation

Description

Functional neuromuscular electrical stimulation (NMES) involves the use of an orthotic device with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function to patients with damaged or destroyed nerve pathways (eg, spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy).

FDA REGULATORY STATUS

In 1997, the Freehand® System was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The implantable Freehand® System is no longer marketed in the United States. The Handmaster NMS I system (now named NESS H200®) was originally cleared for marketing by FDA through the 510(k) process for maintaining or improving range of motion, reducing muscle spasm, preventing or retarding muscle atrophy, providing muscle re-education, and improving circulation (K022776); in 2001, its 510(k) marketing clearance was expanded to include provision of hand active range of motion and function for patients with C5 tetraplegia. FDA product code: GZC.

The WalkAide® System (Innovative Neurotronics, Gainesville, FL; formerly NeuroMotion) was first cleared for marketing by FDA through the 510(k) process in the 1990s (K052329); the current version of the WalkAide® device received 510(k) marketing clearance in 2005. The ODFS® (Odstock Dropped Foot Stimulator; Odstock Medical, Salisbury, U.K.) received 510(k) marketing clearance in 2005 (K050991). The NESS L300® (Bioness, Valencia, CA) was cleared for marketing by FDA through the 510(k) process in 2006. In 2015, the MyGait® Stimulation System (Otto Bock HealthCare, Duderstadt, Germany) received 510(k) marketing clearance (K141812). FDA summaries of the devices state that they are intended for patients with footdrop and assist with ankle dorsiflexion during the swing phase of gait. FDA product code: GZI.

To date, 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.

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 footdrop 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.

BENEFIT APPLICATION

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

This policy does not refer to commercially available exercycles that use electrical muscle stimulation technology as a means of physical therapy and exercise for patients with spinal cord injury. These exercycles are sometimes called functional neuromuscular exercisers. The goals for using these devices may be to promote cardiovascular conditioning, prevent muscle atrophy, and/or maintain bone mass. The patient's legs are wrapped in fabric strips that contain electrodes to stimulate the muscles, thus permitting the patient to pedal.

RATIONALE

Summary of Evidence

For individuals who have loss of hand and upper-extremity function due to SCI or stroke who receive functional NMES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. Evidence on functional NMES 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 NMES outside the investigational setting. It is uncertain whether NMES can restore some upper-extremity function or improve the quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic footdrop who receive functional NMES, the evidence includes randomized controlled trials and a systematic review. Relevant outcomes are functional outcomes and quality of life. For chronic poststroke footdrop, 2 large randomized trials have shown improved patient satisfaction with NMES; however, in objective measures (eg, walking), no significant difference has been observed between NMES and a standard ankle-foot orthosis. A small randomized trial examining neuromuscular stimulation for footdrop in patients with multiple sclerosis revealed a clinically significant reduction in falls; the trial also revealed an improvement in patient satisfaction with the neuromuscular stimulation (as opposed to an exercise program). However, in the area of walking speed, the trial failed to demonstrate a clinically significant benefit to the neuromuscular stimulation over an exercise class. Studies in a larger number of patients are needed to provide greater certainty about the generalizability of this health outcome. The literature on NMES for footdrop in children with cerebral palsy includes a systematic review of small studies that feature within-subject designs; additional study in a larger number of subjects is needed. Overall, there is insufficient evidence for some indications, and a lack of improvement in objective measures for others. 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 functional NMES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. No controlled trials were identified on functional NMES 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, quality of life) have not been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

In 2009, the National Institute for Health and Care Excellence 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

In 2002 (updated in 2006), Medicare issued a national coverage policy recommending coverage for neuromuscular electrical stimulation (NMES) for ambulation in spinal cord injury patients consistent with the Food and Drug Administration labeling for the Parastep device.[31] 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

Date	Action	Description
December 2011	New Policy	
June 2012	Update Policy	Policy statement changed to read not medically necessary. Related policies added. References 25, 27 added.
June 2013	Update Policy	Policy updated with literature review; references 11-12 and 29-31added; congenital disorders, cerebral palsy added to policy statement.
June 2014	Update 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	Update Policy	Policy was updated with literature review, adding references 20 and 21. Policy statement is unchanged.
December 2017	Update Policy	Policy updated with literature review through June 22, 2017; reference 1 added. Policy statement unchanged.
June 2018	Update 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.