DRAFT Medical Coverage Policy | Functional Neuromuscular Electrical Stimulation



EFFECTIVE DATE: 09/01/2023 **POLICY LAST UPDATED:** 05/05|2023

OVERVIEW

Neuromuscular electrical stimulation (NMES) involves the use of a device that transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of these devices, NMES and functional electrical stimulation (FES). NMES stimulates the muscle when the patient is in a resting state to treat muscle atrophy. FES is used to enhance functional activity of neurologically impaired patients. FES is used to enhance the ability in spinal cord injury (SCI) patients to walk. These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence.

This policy applies to Commercial Products only. For Medicare Advantage Plans, refer to the Related Policies section.

MEDICAL CRITERIA

Commercial Products Not applicable

PRIOR AUTHORIZATION

Commercial Products Not applicable

POLICY STATEMENT

Commercial Products

Neuromuscular stimulation (NMES/FES) is considered not medically necessary as a technique to restore function following nerve damage or nerve injury, as a technique to provide ambulation in patients with spinal cord injury; or to provide ambulation in patients with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., poststroke, or in those with multiple sclerosis), as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable durable medical equipment or not medically necessary/not covered benefits/coverage.

BACKGROUND

NMES involves the use of a device that transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of neuromuscular stimulation. NMES is one type of device that stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type, FES, is used to enhance functional activity of neurologically impaired patients to treat spinal cord injuries.

Neural prosthetic 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, and grasp. Functional neuromuscular stimulators are closed-loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities such as walking. These are contrasted with open-loop systems, which are used for simple tasks such as muscle strengthening alone, and typically in healthy individuals with intact neural control.

One application of functional NMES is to restore upper extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadriplegia). The Neurocontrol Freehand System is an implantable upper extremity neuroprosthesis intended to improve a patient's ability to grasp, hold, and release objects and is indicated for use in patients who are tetraplegic due to C5 or C6 spinal cord injury. The implantable Freehand System is no longer marketed in the U.S., though the company provides maintenance for devices already implanted. The Handmaster NMS I (neuromuscular stimulator) is another device that uses surface electrodes and is purported to provide hand active range of motion and function for patients with stroke or C5 tetraplegia.

Other neural prosthetic devices have been developed for functional NMES in patients with foot drop. Foot drop is weakness of the foot and ankle that causes reduced dorsiflexion and difficulty with ambulation. It can have various causes such as cerebral palsy, stroke, or multiple sclerosis (MS). Functional electrical stimulation of the peroneal nerve has been suggested for these patients as an aid in raising the toes during the swing phase of ambulation. With these devices, a pressure sensor detects heel off and initial contact during walking. A signal is then sent to the stimulation cuff, initiating or pausing the stimulation of the peroneal nerve, which activates the foot dorsiflexors. Examples of such devices used for treatment of foot drop are the Innovative Neurotronics's (formerly NeuroMotion Inc.) WalkAide[®], Bioness' radiofrequency controlled NESS L300TM, and the Odstock Foot Drop Stimulator.

Another application of functional electrical stimulation is to provide spinal cord-injured patients with the ability to stand and walk. Generally, only spinal cord injury patients with lesions from T4 to T12 are considered candidates for ambulation systems. Lesions at T1 to T3 are associated with poor trunk stability, while lumbar lesions imply lower-extremity nerve damage. Using percutaneous stimulation, the device delivers trains of electrical pulses to trigger action potentials at selected nerves at the quadriceps (for knee extension), the common peroneal nerve (for hip flexion), and the paraspinals and gluteals (for trunk stability). Patients use a walker or elbow-support crutches for further support. The electrical impulses are controlled by a computer microchip attached to the patient's belt that synchronizes and distributes the signals. In addition, there is a finger-controlled switch that permits patient activation of the stepping.

Other devices include a reciprocating gait orthosis with electrical stimulation. The orthosis used is a cumbersome hip-knee-ankle-foot device linked together with a cable at the hip joint. The use of this device may be limited by the difficulties in putting the device on and taking it off.

Neuromuscular stimulation is also proposed for motor restoration in hemiplegia and treatment of secondary dysfunction (e.g., muscle atrophy and alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways.

Functional NMES is a method being developed to restore function to patients with damaged or destroyed nerve pathways (e.g., stroke, spinal cord injury, multiple sclerosis, cerebral palsy) through use of an orthotic device with microprocessor-controlled electrical stimulation. Evidence for neuromuscular stimulation to provide functional movement in patients with spinal cord injury is limited by the small number of subjects studied to date. For chronic poststroke foot drop, a large randomized controlled trial and crossover study of NMES versus ankle-foot orthosis (AFO) show improved satisfaction with NMES but no change in objective measures of walking. A small randomized trial examining neuromuscular stimulation for foot drop in patients with MS showed a reduction in falls and improvement in satisfaction when compared with a program of exercise, but did not demonstrate a clinically significant benefit in walking speed. The literature on NMES in

children with cerebral palsy includes a systematic review of small studies with within-subject designs; additional study in a larger number of subjects is needed. Due to insufficient evidence for some indications, and a lack of improvement for others, functional NMES remains not medically necessary.

CODING

The following HCPCS Codes are not medically necessary for Commercial Products:

- **E0764** 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
- **E0770** Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

RELATED POLICIES

Prior Authorization via Web-Based Tool for Durable Medical Equipment (DME) Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations

PUBLISHED

Provider Update, July 2023 Provider Update, July 2022 Provider Update, July 2021 Provider Update, July 2020 Provider Update, August 2019

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