Medical Coverage Policy | Functional Neuromuscular Electrical Stimulation

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OVERVIEW

Neuromuscular Electrical Stimulation, (NMES), involves the use of a device which 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 FES. NMES stimulates the muscle when the patient is in a resting state to treat muscle atrophy. Functional electrical stimulation,(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.

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare only

POLICY STATEMENT

BlueCHiP for Medicare
NMES, Neuromuscular Electrical Stimulation, may be considered medically necessary for the treatment of muscle atrophy when the medical criteria below is met

FES, Functional Electrical Stimulation, may be considered medically necessary for the treatment of spinal code injury when the medical criteria below is met

NMES/FES are not medically necessary for all other indications as there is insufficient peer reviewed scientific literature that demonstrates that the procedure/service is effective.

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 footdrop caused by congenital disorders (eg. cerebral palsy) or nerve damage (eg. portstroke, or in those with multiple sclerosis), as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

> **NOTE:** Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates scientific evidence with local expert opinion, and consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations and the US Congress. BCBSRI policy is based upon peer-reviewed, scientifically controlled studies in the literature which demonstrate the superior health outcome of a service or treatment. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. BCBSRI and Medicare policies may differ; however, our BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers. (In some, but not all instances, BCBSRI offers more benefits than does Medicare).

MEDICAL CRITERIA

BlueCHiP for Medicare

Spinal cord injury (SCI)

FES, for walking is covered in spinal cord injury (SCI) patients when all of the criteria listed below is met

- Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);
- 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;
- Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;
- Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;
- Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;
- Persons that can demonstrate hand and finger function to manipulate controls;
- Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
- .Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
- Persons who have demonstrated a willingness to use the device long-term.

Muscle atrophy;

NMES, for the treatment of muscle atrophy is covered when one of the criteria below is met: ~~limited to~~ :

- Treatment of disuse atrophy where nerve supply to the muscle is intact, including;
  - Brain, spinal cord and peripheral nerves, and
  - Other non-neurological reasons for disuse atrophy. (some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions and hip replacement surgery until orthotic training begins).

BACKGROUND

NMES involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of NMES. NMES/FES is one type of device that stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type, NMES, 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 footdrop. Footdrop 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. In 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 footdrop are the Innovative Neurotronics's (formerly NeuroMotion Inc.) WalkAide®, Bioness' radiofrequency controlled NESS L300™, and the Odstock Foot Drop Stimulator. An implantable peroneal nerve stimulator system (ActiGait) is being developed in Europe.

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 (eg, muscle atrophy and alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways.

Functional neuromuscular electrical stimulation (NMES) is a method being developed to restore function to patients with damaged or destroyed nerve pathways (eg, stroke, spinal cord injury, multiple sclerosis [MS], 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 footdrop, 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 footdrop 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.

The Centers for Medicare and Medicaid Services (CMS) state that NMES, to treat muscle atrophy, is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord, and peripheral nerves. It is also used for other non-neurological reasons for disuse atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue (as in burn lesions), and hip replacement surgery (until orthotic training begins).

FES is limited to SCI patients for walking, who have completed a training program consisting of at least 32 physical therapy sessions with the device over a period of three months. The physical therapy trial period is necessary for the treating physician to accurately assess the patient's ability to use the devices frequently and

over a long period of time. Physical therapy, necessary to perform this training, must be directly performed by the physical therapist as part of a one-on-one training program. The goal of physical therapy must be to train SCI patients on the use of FES devices to achieve walking, not to reverse or retard muscle atrophy.

Therapists with sufficient support skills are only allowed to provide these services in the following settings: inpatient hospitals, outpatient hospitals, comprehensive outpatient rehabilitation facilities, and outpatient rehabilitation facilities.

COVERAGE

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

CODING

The following HCPCS Codes are covered for BlueCHiP for Medicare members only and 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 (this is specific to a functional neuromuscular stimulator, such as the ParaStep, to be used in spinal cord injury patients as an aid in ambulation)

E0770: Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (this is meant to be used for neuromuscular stimulation devices such as the BionessNE)

RELATED POLICIES

None

PUBLISHED

Provider Update	Dec 2014
Provider Update	Aug 2012
Provider Update	Feb 2012
Provider Update	Nov 2010
Provider Update	Oct 2009
Policy Update	Sept 2008
Policy Update	May 2001

REFERENCES

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