Status
Active

Medical and Behavioral Health Policy
Section: Allied Health
Policy Number: VII-11
Effective Date: 01/22/2014

FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION DEVICES

Description: Functional Neuromuscular Electrical Stimulation (FES) attempts to replace stimuli from destroyed nerve pathways with sequential electrical stimulation of muscles through surface electrodes. Upper extremity surface FES devices are designed to activate muscles of the paralyzed forearm and hand, while lower extremity surface FES devices are designed to improve or restore ambulation or to alleviate foot drop.

To date, the Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval (PMA) from the U.S. Food and Drug Administration (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." Using percutaneous stimulation, the Parastep 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). In addition, 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. Moreover, there is a finger-controlled switch that permits patient activation of the stepping.

Other devices used to provide ambulation include a reciprocating gait orthosis (RGO) with electrical stimulation. The orthosis used is a rather 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.

Foot drop is weakness of the foot and ankle, resulting in reduced dorsiflexion and difficulty with ambulation. Foot drop may be caused by stroke or nerve injury. Functional neuromuscular stimulation of the peroneal nerve has been suggested for patients with foot drop as an aid in raising the toes during the swing phase of ambulation. Examples of such devices are the Innovative Neurotronics' (formerly NeuroMotion, Inc.) WalkAide, Bioness NESS L300, and the Odstock Dropped Foot Stimulator. All of these devices have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA). The FDA summaries for the devices state that they are intended to be used in patients with drop foot by assisting with ankle dorsiflexion during the swing phase of gait.

Policy:

Use of an upper extremity functional neuromuscular stimulation device (e.g., NESS H200 or the Handmaster) in the home setting may be considered **MEDICALLY NECESSARY** for the following indications when documented improvement has been shown in the supervised rehabilitation setting:

- Upper limb paralysis due to cervical spinal cord injury;
- Chronic (>6 months) upper extremity paresis due to stroke

Use of an upper extremity functional neuromuscular electrical stimulation device (e.g., NESS H200™ or the Handmaster™) in the home setting for any other indications is considered **INVESTIGATIVE** due to a lack of evidence demonstrating its impact on improved health outcomes.

Use of a lower extremity functional neuromuscular stimulation device (e.g., ParaStep, NESS L300, WalkAide, Odstock Dropped Foot Stimulator) in the home setting is considered **INVESTIGATIVE** as a technique to restore nerve function and provide ambulation following nerve damage or nerve injury in all situations, including but not limited to, the following:

- spinal cord injury; and
- foot drop caused by nerve damage (e.g., post-stroke or in patients with multiple sclerosis).

Coverage:

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

FES devices designed as ergometers, including but not limited to the FES Power Trainer, ERGYS, REGYS, NeuroEDUCATOR, STimMaster Galaxy, and RT300 motorized FES ergometer, are considered to be exercise equipment. Most plans exclude coverage of exercise equipment; please check benefit plan for details.

Coding:

The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPCS:

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

Policy History:

Developed September 10, 2003

Most recent history:
Reviewed January 12, 2011
Reviewed/Updated, no policy statement changes January 11, 2012
Reviewed/Updated, no policy statement changes January 9, 2013
Reviewed January 8, 2014

Cross Reference: