MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

Policy Number: PA.042.MH Last Review Date: 08/04/2016 Effective Date: 09/01/2016

PA.042.MH – Neuromuscular Electrical Stimulators (Medicare Only)

This policy applies to the following lines of business:

✓ MedStar MA – DSNP – CSNP

MedStar Health considers Neuromuscular Electrical Stimulators (NMES) for treatment of Muscle Atrophy medically necessary for the following indications:

- 1. Nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and
- 2. Reason for disuse atrophy is non-neurological. Examples of non-neurological disuse atrophy include:
 - Casting or splinting of limb
 - Contracture due to scarring of soft tissue as in burn lesions
 - Hip replacement surgery (until training begins)

NMES/FES for Walking in Patients with Spinal Cord Injury (SCI):

Specific NMES/FES Product Criteria:

Parastep® (Parastep I)

Coverage of Parastep® I is limited to members with SCI to enable walking and who meet all of the general criteria below.

NESS 300 (Bioness, Ness L-300™)

Coverage of NESS 300 (Bioness, Ness L-300™) is limited to members with foot drop due to SCI and who meet all of the general criteria below.

WalkAide®

Coverage of the Walkaide® is limited to members with foot drop due to SCI and who meet all of the general criteria below.

General NMES/FES Criteria for Use Walking in Patients with SCI:

For approval of NMES/FES, all of the following must be met:

- 1. Intact lower motor neuron units (L1 and below) (both muscle and peripheral nerve), and
- 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, and
- 3. Brisk muscle contraction to NMES, and have sensory perception electrical stimulation sufficient for muscle contraction; and



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- 4. High motivation, commitment and cognitive ability to use such devices for walking, and
- 5. Ability to transfer independently and demonstrate independent standing tolerance for at least three minutes, and
- 6. Demonstrate hand and finger function to manipulate controls, and
- 7. Willingness to use the device long-term, and
- 8. At least six month post recovery SCI and restorative surgery, and
- 9. No hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis, and
- 10. Completion of a training program which consists of at least 32 physical therapy sessions with the device over a three month period (this trial period of physical therapy will enable the SCI treating physician to properly evaluate the person's ability to use the device frequently and for the long term).

Limitations of NMES/FES Used for Walking in Patients with SCI:

- The training must be directly performed by a physical therapist as part of a one-toone training program. The goal of this physical therapy must be to train SCI members on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy.
- 2. The training program must be conducted in an inpatient hospital, outpatient hospital, or comprehensive outpatient rehabilitation facility.
- 3. NMES/FES devices for walking will not be not covered in SCI members with any of the following:
 - Persons with cardiac pacemakers;
 - Severe scoliosis or severe osteoporosis;
 - Skin disease or cancer at area of stimulation;
 - Irreversible contracture; or
 - Autonomic dysflexia.

Background

Neuromuscular Electrical Stimulators (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. The stimulation bypasses the central nervous system and targets motor neurons innervating either skeletal muscle or other organ systems. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients.

These devices use electrical impulses to activate paralyzed or weak muscles in precise sequence and have been utilized to provide SCI patients with the ability to walk. This technology is utilized for both upper extremity (e.g., improved hand grasp function) and



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lower extremity rehabilitation, but the current decision memorandum is focused upon a very specific lower extremity application, to enhance standing and walking. NMES used for this indication is also commonly called functional electrical stimulation (or FES). NMES is used to assist standing and ambulation in paraplegics or quadriplegics who have adequate use of their upper extremities to allow balancing with a walker (or with elbow-support crutches), assuming satisfactory pulmonary and cardiovascular functioning.

Examples of Food and Drug Administration (FDA) approved external functional neuromuscular stimulators may include but not limited to:

- Parastep I
- RT300
- WalkeAide
- NESSL300
- NESS H200

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
E0745	Neuromuscular stimulator, electronic shock unit
E0764	Functional neuromuscular stimulator, 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

References

- Bioness: NESS L300 Drop Foot System, Indications, Contraindications, Warnings, Precautions and Adverse Reactions. Accessed: 6/19/2013. http://www.bioness.com/Documents/CombinedIndicationsBenefitsandContraindications.pdf. Product brochure:
 http://www.bioness.com/Documents/L300Consumer/Product_Packets_DTC_NE_SS_L300.pdf



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- Christopher & Dana Reeve Foundation Paralysis Resource Center: Parastep, 4/03. http://www.christopherreeve.org/atf/cf/%7B3d83418f-b967-4c18-8ada-adc2e5355071%7D/ParaStep%207-08.PDF
- 4. CMS Healthcare Common Procedure Coding System (HCPCS) Public Meeting Summary Report. Durable Medical Equipment (DME), Attachment # 08.41, 5/28/2008.
- Deaconess Health System: NESS L300, Accessed: 7/2/2013. http://www.deaconess.com/HealthsouthDeaconessHospital/Advanced-Technology/NESS-L300.aspx
- 6. Innovative Neurotronics: WalkAide, Accessed: 4-30-2009. http://www.walkaide.com/en-US/Pages/default.aspx
- 7. Innovative Neurotronics: FAQs About the WalkAide and Innovative Neurotronics Inc.5/06. http://www.walkaide.com/en-US/Patients/Pages/FAQs.aspx
- 8. FDA 510(k) Summary: NESS- L300, 1/29/2008. http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080219.pdf
- 9. FDA Drug and Device Product Approvals: Parastep. PMA Approval Number: P900038.
 - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=17995
- 10. Hayes. Functional Electrical Stimulation for Rehabilitation Following Spinal Cord Injury. Reviewed January 14, 2015.
- 11. Mayo Clinic: Spinal cord injury (definition), Access from website on July 8, 2013. http://www.mayoclinic.com/health/spinal-cord-injury/DS00460
- 12. NHIC, Corp, DME MAC Jurisdiction A: Functional Electrical Stimulators- New Code, Posted: 12/4/2008.

 http://www.medicarenhic.com/dme/medical_review/mr_bulletins/mr_bulletin_current/120408 fes.pdf
- 13. Sigmedics, Inc.: Special Announcement: CMS extends Parastep I System Coverage, dated: 4/1/2003.

 http://www.sigmedics.com/announcement.php Therapeutic Alliances Inc., The Parastep System. Accessed: 4/30/2009.

 http://www.musclepower.com/parastep.htm
- 14. Medicare National Coverage Determinations Manual, Transmittals for Chapter 1, Part 2 (Sections 90-160.26), Rev. 15, 11-30-12. Section 106.12 Neuromuscular Electrical Stimulators (MNES), effective 10-01-06.. http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part2.pdf

Disclaimer:

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