

UPMC Health Plan POLICY AND PROCEDURE MANUAL

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SUBJECT: Functional Electrical Stimulators (Medicare Only)
INDEX TITLE: Medical Management
ORIGINAL DATE: July 2009

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()		POS ()		PPO ()	
Fully Insured ()		Self-funded/ASO ()		HSA ()	
Medicare Select ()		Medicare Supplement ()		OOA/DOC ()	
				All ()	
DPW-MA:					
Health Choices ()			Voluntary ()		All ()
CMS-MA:					
OH ()		WV		PA ()	
All (X)		Other ()			
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS ()	All ()
PID-CHIP:					
Free ()			Sub ()		All ()
APPLICABLE TO:					
Community Care ()			Work Partners ()		

I. POLICY

It is the policy of UPMC Health Plan to recognize coverage for services mandated through Medicare regulations. Coverage for Medicare members for functional electrical stimulators (FES) will be considered after review for medical necessity, according to the indications detailed in this policy and when covered under the member's benefit plan.

All denials are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director (Medical Director).

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the criteria for functional electrical stimulators for Medicare members.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description / Background

Functional Electrical Stimulators (FES) are a type of neuromuscular stimulators (NMES) that are used to enhance the ability to walk in patients with spinal cord injury (SCI). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence.

Parastep I is a microcomputer controlled functional neuromuscular stimulation (FNS) system that enables independent, unbraced ambulation (i.e., standing and walking) by people with a spinal cord injury. It is a non-invasive system and consists of a microcomputer controlled neuromuscular stimulation unit, battery with re-charger, Paratester™ - a unit for pre-testing main system operation and electrode cables, surface applied skin electrodes, power and electrode cables, and a control and stability walker with finger activated control switches. Users hold on to a front wheeled walker fitted with a keypad wired to a microprocessor worn on the belt. Surface electrodes are placed on the quadriceps and gluteal muscles and the peroneal nerves. The user initiates stepping by firing the muscles in the proper sequence. Stimulation of the quadriceps causes a contraction that result in knee extension, enabling the user to stand. Stimulation of leg nerves initiates a contraction to flex the hip, knee, and ankle; this lifts the foot off the floor as quadriceps stimulation then cycles on to extend the knee for taking a step. The FDA has approved this unit for use in restoring ambulation to paraplegics.

Ness 300 (Bioness, Ness L-300™) is a system that stimulates the muscles and nerves that lift the foot. The system has 4 main parts: a leg orthosis (worn on the lower leg and foot) containing electrodes and a RF simulation unit, RF communication and rechargeable battery, a waist mounted or in pocket control unit, including a PDA (clinician programmer) interface, RF communication, AAA rechargeable batteries, a foot/gait sensor with RF communication and non-rechargeable coin battery, and a handheld computer (PDA) that use wireless communication. The gait sensor detects “heel off” and “heel contact” events during gait and transmits signals to the RF stimulating unit. The stimulating unit initiates and pauses the stimulation, activating the foot doriflexors to ensure proper foot clearance during swing phase and proper foot placement during the stance phase. The FDA approved this unit for individuals with foot drop.

WalkAide® is a neural or “smart” prosthesis that stimulates a specific nerve to replace absent brain activity directed towards walking. It uses functional electrical stimulation to restore the typical nerve-to-muscle signals in the leg and foot, effectively lifting the foot at the appropriate time during the gait cycle. The system has a cuff battery-operated, single-channel electrical stimulator, two electrodes, and electrode leads. The FDA has approved this unit for patients with lack of ankle dorsiflexion (foot drop) secondary to an upper motor neuron lesion.

Due to the overall limitation of scientific efficacy for FES in the small body of clinical evidence available, these devices are considered experimental and investigative.

B. Specific Criteria

Parastep® (Parastep I)

Coverage of Parastep® I is limited to members with spinal cord injury (SCI) to enable walking **and** who meet **all** of the below (1-10) criteria.

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 below (1-10) criteria.

WalkAide®

Coverage of the Walkaide® is limited to members with foot drop due to SCI **and** who meet **all** of the below (1-10) criteria.

Criteria

1. Member has intact lower motor neuron units (both muscle and peripheral nerve), L1 and below, **and**
2. Member has 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. Member demonstrates brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction, **and**
4. Member demonstrates high motivation, commitment and cognitive ability to use such devices for walking, **and**
5. Member can transfer independently and can demonstrate independent standing tolerance for at least three (3) minutes, **and**
6. Member can demonstrate hand and finger function to manipulate controls, **and**
7. Member demonstrates a willingness to use the device long-term, **and**
8. Member is at least six (6)-month post recovery spinal cord injury and restorative surgery, **and**
9. Member does not have hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis **and**
10. Member has completed a training program which consists of at least 32 physical therapy sessions with the device over a 3 month period, **and** the trial period of physical therapy will enable the physician treating the member for the SCI to properly evaluate the person's ability to use the device frequently and for the long term.

Note: The training program must be conducted in an inpatient hospital, outpatient hospital or outpatient rehabilitation facility.

C. Limitations

1. Physical therapy necessary to perform the training must be directly performed by a physical therapist as part of a one-to-one training program. The goal of physical therapy is to train SCI patients on the use of FES devices to achieve walking, not to reverse or retard muscle atrophy.
2. FES devices for walking are **not covered** in SCI members with any of the following:

- Skin disease or cancer at area of stimulation,
- Persons with cardiac pacemakers,
- Severe scoliosis or severe osteoporosis,
- Irreversible contracture,
- Autonomic dysflexia.

D. Information Required for Review

1. A physician's prescription or letter of medical necessity.
2. Documentation supporting the member's need for a FES, including:
 - History and physical and diagnosis
 - Date of spinal cord injury and confirmation of lower neuron motor unit function
 - Date of restorative surgery for SCI
 - Member's balance, control and transfer status and ability to stand independently for three (3) minutes
 - Member's muscle contraction and sensory perception status
 - Member's joint stability for weight bearing and maintenance of independent upright posture
 - Member's motivation level and cognitive ability and commitment to use the device
 - Member's hand and finger coordination status
 - Dates of training program performed by a physical therapist, including completion date and facility location
 - No history of degenerative joint disease or pathological fractures.

E. Review Process

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to a Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Variations

Experimental and Investigational for Commercial, Medical Assistance and CHIP products.

G. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

H. References

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<http://www.christopherreeve.org/atf/cf/%7B3d83418f-b967-4c18-8ada-adc2e5355071%7D/ParaStep%207-08.PDF>
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16. ECRI Hotline: Neuromuscular Electrical Stimulation for Mobility and Motor Function following Spinal Cord Injury, 10/8/09.

Disclaimer:

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

UPMC Health Plan reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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