INNOVATIVE NEUROTRONICS
"INDEPENDENCE, ONE STEP AT A TIME"

Instructions & Forms for Submitting Claims to Medicare

The Centers for Medicare and Medicaid services have issued a national coverage policy for the WalkAide. CMS will cover patients who have a diagnosis of Incomplete Spinal Cord Injury. All other indications are still considered a non-covered service by Medicare and an Advance Beneficiary Notice (ABN) must be obtained PRIOR to collecting monies from the patient.

In order for Medicare to cover services for this patient population; the criteria listed below must be met prior to a clinician submitting a claim for the WalkAide to Medicare.

Coverage for NMES/FES for walking will be covered in SCI patients with all of the following characteristics: *NCD coverage for CMS 160.12*

1. *Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);*
2. *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;*
3. *Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;*
4. *Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;*
5. *Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;*
6. *Persons that can demonstrate hand and finger function to manipulate controls;*
7. *Persons with at least 6-month post recovery spinal cord injury and restorative surgery;*
8. *Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and*
9. *Persons who have demonstrated a willingness to use the device long-term.*
10. *Coverage for the use of NMES/FES is limited to SCI patients for walking, who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months. The trial period of physical therapy will enable the physician treating the patient for his or her spinal cord injury to properly evaluate the person's ability to use these devices frequently and for the long term. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program.*

Once all the requirements are met, the Physical Therapist will designate that the patient has satisfied the requirements and documentation will be kept in the patients file.

(Attachment 1 *PT acknowledgement of completion* sample) Under the NCD, Incomplete Spinal Cord Injury patient rehab for FES is not subject to the cap and is considered an exclusion from such cap. (Please see reference document 2 Medicare Claim Processing Manual, Section 10.2 (1)(2) pgs. 13-21)

Innovative Neurotronics has provided a Physical Therapy Guide to assist in treatment protocols for Incomplete Spinal Cord patients. (Attachment 2 *Guideline for PT*)

Coding for replacement electrodes would use the existing code of A4595. The A4595 code is for two electrodes. The average one month supply of WalkAide electrodes is a quantity of four. If four electrodes are used by a patient for a one month supply for the WalkAide; A4595 x 2 would be submitted on the claim form.

Submitting Claims to Medicare for the WalkAide or Electrodes

Medicare will only cover patients who have a diagnosis of an incomplete spinal cord injury. All other conditions are considered non-covered by Medicare.

For submitting claims to Medicare:

Incomplete Spinal Cord Injury- If the patient has met all the criteria outlined the Reimbursement Guide; The claim would be filled with the E0770 code and a KX modifier acknowledging the patient has satisfied all the requirements and is an appropriate candidate. Please note: medical documentation may be requested by Medicare to substantiate the claim. If the KX modifier is not on the claim, Medicare will deny the claim as not medically necessary.

For submitting claims on other indications:

All other conditions still remain non-covered by Medicare. Patients will need to complete the Advance Beneficiary Notice (ABN) and attach a copy to the claim. Submit the claim as Non-Assigned and have the patient pay as self-pay.

Requirements for Billing DME

In order to bill for DME services, practices must be an accredited or certified facility in accordance with the CMS regulations by September 30, 2009. Many providers are in the process or have already had site certification by some of the accrediting bodies such as ABC or BOC. Both agencies are able to provide additional certification for DME in addition to O & P certification. In addition, some states have additional requirements in order to sell a prescriptive device and or DME product.

**Please verify with your State Health and Safety Department if additional requirements are required to sell DME devices.

WalkAide Reimbursement Guide

- A4595 have limits on the amount that can be billed. Medicare DME guidelines allow a one month supply to be billed for each patient.
- Other payers may allow for a greater number of electrodes to billed as this represents a cost savings to the payer and patient.
- Medicare fee schedule is based off of DME Carrier Jurisdiction B. Rates and Allowables will vary dependent on geography.
- WalkAide procedures should be billed on separate claims. Other procedures should not be included.

DISCLAIMER

Innovative Neurotronics has provided this reimbursement guide for our customers. This guide does not replace seeking guidance for the payer or your coding staff. The responsibility for correct coding is that of the provider of service. Please contact your local payer for any interpretation of coding for any device or procedure. Innovative Neurotronics Inc. makes no guarantees that the use of this information will prevent disputes from Medicare or other Third Party Payers as to correct coding or the amount that will be paid to providers.

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Attachment 1

Physical Therapy Acknowledgement of Completion Required for Medicare Beneficiaries Receiving Services.

Facility Name_____

Facility Address _____

Facility Phone Number _____

PT Provider of Service _____

Patient Name _____

In order for patients to receive coverage for the WalkAide device, CMS requires that the following instructions and requirements need to be met. A copy of the CMS coverage policy outlining the below mentioned has been included for your convenience.

The goal of physical therapy must be train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy.

Coverage for NMES/FES for walking will be covered in SCI patients with all of the following characteristics:

1) Persons with intact lower motor units(L1 and below) (both muscle and peripheral nerve);

2) 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;

3) Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;

4) Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

5) Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;

6) Persons that can demonstrate hand and finger function to manipulate controls;

7) Persons with at least 6-month post recovery spinal cord injury and restorative surgery;

8) Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and

9) Persons who have demonstrated a willingness to use the device long-term.

10) Patients must complete a training program which consists of at least 32 physical therapy sessions with the device over a period of three months.

In addition, the only setting where therapists with sufficient skills to provide these services are employed are inpatient or outpatient hospitals, comprehensive outpatient rehab facilities or (CORF) and outpatient rehab facilities. PT necessary to perform this training must be part of a one-on-one training program.

Once these requirements are met, please sign this form and fax to Innovative Neurotronics Inc. Fax 512 721 1970 or Email reimbursement@ininc.us and the designated clinician.

_____ _____ _____

PT Name Date PT Signature

Thank you for participating in the care of this patient to help realize the importance of the goal in restoring function to each patient.

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Attachment 2

Physical Therapy Guidelines for WalkAide® Patients – Incomplete SCI

The following therapeutic and functional goals must be met before a patient can be considered competent in daily WalkAide wear and use. These goals must be completed during 32 sessions of physical therapy. CMS has established coverage requirements in order for the device to be reimbursed for incomplete spinal cord patients

I. Programming

1. If patient is referred with a preliminary WalkAide program; The PT will open that programming file, send it to their clinical WalkAnalyst and evaluate the fit of that program to that patient's gait. Modifications should be made; it may be necessary to better optimize the specific patient program with the clinician's WA. (Tilt sensor calibration differences between WalkAide devices exist; modification of program may be necessary between devices.)
2. If the patient is not referred with an initial program, the Physical Therapist will be responsible for programming the clinical device for that specific patient. That program will serve as the base for training throughout the physical therapy sessions.
3. The programming phase shall include patient education in applying the electrodes to the WA cuff and donning and doffing WA cuff.

Goals for Programming Phase/Timeframes

1. WalkAide can generally be programmed to fit patient's gait within 4 sessions.
2. Patients dependent on ability and cognitive function; will be independent in applying electrodes to cuff/changing electrodes within 8 sessions.
3. Patient will be able to demonstrate an independent understanding of when electrodes need to be changed either because of time (usually 40 hours of wear) or electrode condition (electrodes are worn or dirty) within 8 sessions.
4. Patient should be able to independently don and doff WA cuff within 8 sessions.
5. Patient will be able to don cuff, check stimulation to determine appropriateness of electrode placement, stand, and initiate gait with consistent stimulation independently 8 to 10 sessions. .

II. Gait training

1. Gait training should include but may not be limited to the following:

- Training to improve the symmetry of stance and swing phases given the assistance to swing provided by the WA.
- Training to equalize weight shifting from side to side during gait.

- Training to decrease compensatory motions (hip hike, circumduction, lateral/posterior lean, etc.).
- Functional training/exercise to improve pelvic stability and LE stability during stance.
- Motor relearning training to facilitate appropriate control/coordination of flexor and extensor synergies.
- Functional training and or mobilization to decrease abnormal tone and facilitate normal movement and postural reactions.

***Programming changes may need to occur as patient improves with gait or as motor control increases.*

Goals for Gait Training Phase/Timeframes

1. Patient will be independent with gait using the WA and appropriate assistive devices on level surfaces for 100 feet within 12 sessions.
2. Pt will demonstrate consistent stimulation during every swing and will be able to independently restart straight away gait from a stop or turn without missing a stimulation within 12 sessions.
3. Pt will be independent in an appropriate home exercise program for strengthening and/or motor control within 12-16 sessions.
4. Pt will be independent in managing ramps, stairs and uneven terrain using the WA and appropriate assistive devices within 16-20 sessions.
5. Pt will be independent with gait WA and appropriate assistive devices on level surfaces for 300 feet within 20-24 sessions.
6. Pt will demonstrate an ability to increase and decrease speed appropriate to architectural and community barriers within 24-26 sessions.
7. Pt will exhibit improved motor control and coordination as evidenced by a decrease in abnormal synergistic motion within 26-28 sessions.
8. Pt will exhibit a decrease in compensatory movement patterns as evidenced by symmetrical weight shifting bilaterally, symmetrical rotation and elevation of pelvis during gait, and symmetrical heel placement and forward weight shift at the beginning of stance within 28-32 sessions.

III. Management of the WalkAide

1. The management phase should include patient education on all WalkAide issues: review of donning and doffing, care of WA device and electrodes, skin care issues, contraindications, trouble shooting and proper initial wear schedule.
2. Final program changes should be made at this point and communicated to the orthotist who will be fitting the patient's final device.

Goals for Management Phase/Time frames

1. Pt will be independent with level and non-level surfaces at a community ambulation level (greater than 350 feet) within 28-32 sessions.
2. Pt will demonstrate the ability to speed up or slow down to manage architectural barriers and community ambulation challenges safely and without losing stimulation consistency with in 28-32 sessions.
3. Pt will ambulate independently with end-stage assistive device within 28-32 sessions.
4. Pt will be independent with turning on/off WA exercise mode and with any exercise program as assigned within 28-32 sessions.
5. Pt will be able to independently verbalize all aspects of WA care, use and maintenance within 28-32 sessions.
5. Pt will be independent in verbalizing concerns with programming to Orthotist or Physical Therapist and with identifying when WalkAide re-programming may be necessary within 30-32 sessions.