

Subject: Functional Electrical Stimulation (e.g., Parastep I System) for Spinal Cord Injury		Original Effective Date: 8/27/14
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Spinal Cord Injury (SCI):

According to the international standards for neurological and functional classification of spinal cord injury, a spinal cord injury (SCI) is an insult to the spinal cord resulting in a change, either temporary or permanent, in its normal motor, sensory, or autonomic function. Definitions include:¹⁶

- Tetraplegia (preferred to “quadriplegia”): This term refers to impairment or loss of motor and/or sensory function in the cervical segments of the spinal cord due to damage of neural elements within the spinal canal. Tetraplegia results in impairment of function in the arms as well as typically in the trunk, legs and pelvic organs, i.e. including the four extremities. It does not include brachial plexus lesions or injury to peripheral nerves outside the neural canal.
- Paraplegia: This term refers to impairment or loss of motor and/or sensory function in the thoracic, lumbar or sacral (but not cervical) segments of the spinal cord, secondary to damage of neural elements within the spinal canal. With paraplegia, arm functioning is spared, but, depending on the level of injury, the trunk, legs and pelvic organs may be involved. The term is used in referring to cauda equina and conus medullaris injuries, but not to lumbosacral plexus lesions or injury to peripheral nerves outside the neural canal.

Functional electrical stimulation (FES):

A treatment modality in which electrical impulses are applied to intact peripheral nerves supplying paralyzed muscles in order to produce functional movement and stimulate contractions of those muscles to promote recovery of motor function. FES systems consist of a stimulator that produces electrical pulses, electrodes that deliver the electric pulses to the appropriate sites, lead wires connecting the stimulator to the electrodes, and a control unit that provides power and commands for the system. FES may be delivered via surface (transcutaneous), percutaneous, or fully implanted systems. In the transcutaneous systems, electrodes are placed on the skin, and the stimulator/control unit is worn on the body. Percutaneous systems use electrodes that are implanted in the muscles for activation. The electrode lead wires pass through the skin and are connected to an external stimulator/control unit that is worn on the body. For fully implanted systems, the electrodes, lead wires, and stimulator are implanted under the skin. Electrodes may be implanted on a muscle surface, within a muscle, or around or adjacent to a nerve. In this case, the stimulator receives power and commands through a radio-frequency telemetry link to an external control unit. For all FES systems, electrodes are placed over or as close as possible to the nerves or motor points of muscles to be activated. For any given muscle, a motor point is the site where electrical stimulation (ES) produces the strongest and most isolated contraction with the lowest level of stimulation.²⁹

The U.S. Food and Drug Administration (FDA) approved the Parastep I (Sigmedics, Inc.), electrical stimulation device for quadriplegics on April 20, 1994 under PMA No. P900038 as a class III device.²

POSITION STATEMENT RECOMMENDATION^{1 2 5-28}

1. Functional Electrical Stimulation (e.g., Parastep I System) may be considered medically necessary and authorized for patients who have spinal cord injury for walking rehabilitation when all of the following criteria is met: [ALL]
 - ☐ Used as part of a comprehensive rehabilitation program and:
 - completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months; and
 - training must be directly performed by the physical therapists as part of a one-on-one training program; and
 - ☐ Be at least 6-month post recovery spinal cord injury and restorative surgery;

- ☐ Have intact lower motor 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
- ☐ Demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;
- ☐ Have high motivation, commitment and cognitive ability to use such devices for walking;
- ☐ Can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;
- ☐ Demonstrate hand and finger function to manipulate controls;
- ☐ No hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
- ☐ Demonstrated a willingness to use the device long-term

2. FES is considered not medically necessary for any of the following clinical conditions: [ALL] ^{1-2 29}

- ☐ Any other diagnosis as the evidence is insufficient to evaluate net outcomes
- ☐ Presence of cardiac pacemakers;
- ☐ Severe scoliosis or severe osteoporosis;
- ☐ Skin disease or cancer at area of stimulation;
- ☐ Irreversible contracture;
- ☐ Autonomic dysflexia;
- ☐ Poorly controlled epilepsy;
- ☐ Pregnancy;
- ☐ Fracture or dislocation near or on the site of application

SUMMARY OF MEDICAL EVIDENCE ⁷⁻²⁸

Evidence pertaining to the effect of functional electrical stimulation (FES) on the general physical fitness and health of patients with spinal cord injury (SCI) consists of several small RCT's and prospective trials that outline the effectiveness of FES in improving various measures of physical function and overall functional status as a means of assisting walking or enhancing gait training in patients with incomplete SCI.

A small RCT (2012) evaluated the effects of functional electrical stimulation (FES)-assisted walking on body composition, compared to a non-FES exercise program in individuals with a spinal cord injury (SCI). 34 individuals with chronic (≥ 18 months) incomplete SCI (level C2 to T12, AIS C or D) were recruited and randomized to FES-assisted walking (intervention), or aerobic and resistance training (control) sessions thrice-weekly for 16 weeks. Results indicated that 3x weekly FES-assisted walking exercise over 4 months did not result in a change in body composition in individuals with chronic, motor incomplete C2 to T12 SCI (AIS classification C and D). However, longer-term follow-up revealed that it might maintain muscle area.⁵

Four RCTs evaluating the effect of FES on changes in muscle strength, body mass, cardiovascular indicators, and bone mineral density (BMD).⁵⁻⁹ The earliest study was among patients with incomplete SCI, while the later three studies were all limited to patients with complete SCI. Two nonrandomized prospective controlled trials evaluating the effect of FES on BMD and fat mass. All participants except for 2 (in the earlier study) had complete SCI.¹⁰⁻¹¹ The primary findings of these six studies showed that FES-assisted lower limb cycling in the early post-injury period prevents loss of lean body mass in patients with complete SCI; 6 weeks of intensive

electrical stimulation to the quadriceps and knee flexion may attenuate BMD loss over the distal femur among patients with complete SCI; 2 weeks of FES-assisted muscle strengthening exercise among patients with very recent complete SCI does not reduce loss in BMD or prevent an increase in fat mass; 3 months of FES cycling significantly decreased the rate of BMD loss at the distal femur among patients with recent complete SCI; FES-assisted upper limb cycling in patients with incomplete tetraplegia is associated with a significantly better likelihood of improving by ≥ 1 grade on the American Spinal Injury Association (ASIA) manual muscle test after 4 and 8 weeks of treatment; and 6 months of FES-assisted lower limb cycling in children with complete SCI at ≥ 1 year post injury does not improve cardiorespiratory health, except for an increase in oxygen uptake, but is associated with a significant trend for increased BMD in the femur. ⁶⁻¹⁰

Additional prospective longitudinal case series studies among patients with complete SCI, with 1 or 2 years follow-up indicated that a full year of FES cycle training brought a significant improvement in bone parameters at the actively loaded distal femur, but not the passively loaded tibia 2 years of FES home-based training brought significant increases in mean quadriceps cross-sectional area, mean diameter of muscle fibers, and mean maximum knee torque, while mean area covered by muscle fibers remained stable. ¹³⁻¹⁵

A RCT to investigate short- and long-term benefits of 16 weeks of 3x weekly FES-assisted walking program, while ambulating on a body weight support treadmill and harness system, versus a non-FES exercise program, on improvements in gait and balance in individuals with chronic incomplete traumatic SCI showed that task-oriented training improves walking ability in individuals with incomplete SCI, even in the chronic stage. ¹⁷

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A

HCPCS	Description
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

ICD-10	Description: [For dates of service on or after 10/01/2015]
G81-G81.9	Hemiplegia
G82-G82.5	Paraplegia & Quadriplegia

RESOURCE REFERENCES

Government Agency

- Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12). Effective date: 10/1/2006. Available at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>

2. Center for Devices and Radiological Health (CDRH). P900038. Parastep-I. April 20, 1994. Food and Drug Administration. Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>.

Professional Society Guidelines

3. National Institute for Health Care and Excellence (NICE). Guidance IPG278. Functional electrical stimulation for drop foot of central neurological origin. 2009. Jan. Updated 2012. Accessed at: <http://www.nice.org.uk/guidance/IPG278/chapter/1-guidance>
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Peer Reviewed Publications

5. Giangregorio L, Craven C, Richards K, et al. A randomized trial of functional electrical stimulation for walking in incomplete spinal cord injury: effects on body composition. *J Spinal Cord Med*. 2012 Sep;35(5):351-60. doi: 10.1179/2045772312Y.0000000041.
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9. Groah SL, Lichy AM, Libin AV, Ljungberg I. Intensive electrical stimulation attenuates femoral bone loss in acute spinal cord injury. *PM R*. 2010;2(12):1080-1087.
10. Lauer RT, Smith BT, Mulcahey MJ, Betz RR, Johnston TE. Effects of cycling and/or electrical stimulation on bone mineral density in children with spinal cord injury. *Spinal Cord*. 2011;49(8):917-923.
11. Clark JM, Jelbart M, Rischbieth H, et al. Physiological effects of lower extremity functional electrical stimulation in early spinal cord injury: lack of efficacy to prevent bone loss. *Spinal Cord*. 2007;45(1):78-85.
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13. Frotzler A, Coupaud S, Perret C, et al. High-volume FES-cycling partially reverses bone loss in people with chronic spinal cord injury. *Bone*. 2008;43(1):169-176.
14. Kern H, Carraro U, Adami N, et al. Home-based functional electrical stimulation rescues permanently denervated muscles in paraplegic patients with complete lower motor neuron lesion. *Neurorehabil Neural Repair*. 2010a;24(8):709-721.
15. Kern H, Carraro U, Adami N, et al. One year of home-based daily FES in complete lower motor neuron paraplegia: recovery of tetanic contractility drives the structural improvements of denervated muscle. *Neurol Res*. 2010b;32(1):5-12.
16. Kirshblum SC1, Burns SP, Biering-Sorensen F, et al. International standards for neurological classification of spinal cord injury (Revised 2011). *J Spinal Cord Med*. 2011 Nov;34(6):535-46.

17. Kapadia N, Masani K, Catharine Craven B. A randomized trial of functional electrical stimulation for walking in incomplete spinal cord injury: Effects on walking competency. *J Spinal Cord Med*. 2014 Sep;37(5):511-24. doi: 10.1179/2045772314Y.00000000263.
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Other Resources

29. Hayes a TractManager Company. Winifred Hayes Inc.

- Functional Electrical Stimulation for Rehabilitation Following Spinal Cord Injury. November, 2017. Updated Feb, 2020.
- Functional Electrical Stimulation (FES) for Treatment of Foot Drop in Multiple Sclerosis Patients. Dec 2011. Updated June 2017. Archived Aug, 2018.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

There is a National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12) that outlines coverage of functional electrical stimulation (FES) that is limited to spinal cord injury (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. ¹

REVIEW/REVISION HISTORY

8/27/14: New Policy

12/16/15, 9/15/16: Policy reviewed, no changes.

8/23/17: The policy was reviewed and the clinical criteria has changed. Poorly controlled epilepsy; Pregnancy; and Fracture or dislocation near or on the site of application were added to the exclusions section. The following sections were updated: Summary of medical evidence, professional guidelines and references.

7/10/18: Policy reviewed, no changes to criteria. Updated professional guidelines.

6/19/19: Policy reviewed, no changes to the criteria. Updated the policy to be specific to the Parastep I System used for spinal cord injury for ease of application. Updated references.

6/17/20, 6/9/21: Policy reviewed, no changes to criteria.