Molina Clinical Policy
Functional Electrical Stimulation (e.g., Parastep I System) for Spinal Cord Injury: Policy No. 205

Last Approval: 6/8/2022
Next Review Due By: June 2023

Ohio Medicaid: Member must be referred to physical therapy without a mandatory number of visits.

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

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:

- **Tetraplegia** (preferred to quadriplegia) is a term referring 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** 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 (Kirshblum et al., 2011).

Functional Electrical Stimulation (FES)

Functional electrical stimulation is 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 (Hayes, 2022).

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 (FDA, 1994).

COVERAGE POLICY

1. Functional Electrical Stimulation (FES) (e.g., Parastep I System) **may be considered medically necessary** and authorized for Members who have a spinal cord injury for walking rehabilitation when **ALL** of the following are met:

   a. Used as part of a comprehensive rehabilitation program including ALL of the following:
      - 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.

   b. Be at least 6-month post recovery spinal cord injury and restorative surgery; **AND**
   a. Have intact lower motor units (L1 and below) (both muscle and peripheral nerve); **AND**
   b. 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**
   c. Demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction; **AND**
   d. Have high motivation, commitment and cognitive ability to use such devices for walking; **AND**
   e. Can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes; **AND**
   f. Demonstrate hand and finger function to manipulate controls; **AND**
   g. No hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; **AND**
   h. Demonstrated a willingness to use the device long-term.

2. FES is considered **not medically necessary** for **ANY** of the following clinical conditions:
   a. Any other diagnosis as the evidence is insufficient to evaluate net outcomes; **OR**
   b. Presence of cardiac pacemakers; **OR**
   c. Severe scoliosis or severe osteoporosis; **OR**
   d. Skin disease or cancer at area of stimulation; **OR**
   e. Irreversible contracture; **OR**
   f. Autonomic dysflexia; **OR**
   g. Poorly controlled epilepsy; **OR**
   h. Pregnancy; **OR**
   i. Fracture or dislocation near or on the site of application.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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 RCTs 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 patient with incomplete SCI.

A small RCT 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 (Giangregorio et al., 2012).

Four RCTs evaluating the effect of FES on changes in muscle strength, body mass, cardiovascular indicators, and bone mineral density (BMD) (Giangregorio et al., 2012; Needham-Shropshire et al, 1997; Baldi et al., 1998; Johnston et al., 2009; Groah et al., 2010). The earliest study was among patients with incomplete SCI, while the later three studies were limited to patients with complete SCI. Two non-randomized prospective controlled trials evaluated the effect of FES on BMD and fat mass. All participants except for 2 (in the earlier study) had complete SCI (Lauer et al, 2011; Clark et al., 2007). 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.

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 (Frotzler et al., 2008; Kern et al., 2010a; Kern et al., 2010b).

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 (Kapadia et al., 2014).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes – None.

HCPCS Codes

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

6/8/2022	Policy reviewed, no changes.
6/9/2021	Policy reviewed, no changes.
6/17/2020	Policy reviewed, no changes.
6/19/2019	Policy reviewed. Inclusion of Parastep I System for spinal cord injury for ease of application; references updated.
7/10/2018	Policy reviewed, no changes. Updated professional guidelines.
8/23/2017	Policy was reviewed; clinical criteria changed. Poorly controlled epilepsy; pregnancy; and fracture or dislocation near or on the site of application were added to the exclusions section. The Summary of Medical Evidence was also updated.
9/15/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
8/27/2014	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). National coverage determination (NCD) for neuromuscular electrical stimulation (NMES) (160.12). Available from CMS. Effective October 1, 2006.
2. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). P900038: Parastep-I. Available from FDA. Published April 20, 1994.

National and Specialty Organizations

1. National Institute for Health Care and Excellence (NICE). Guidance IPG278: Functional electrical stimulation for drop foot of central neurological origin. Available from NICE. Published January 2009. Updated 2012.
2. Fehlings M, Tetreault L, Aarabi B, et al. A clinical practice guideline for the management of patients with acute spinal cord injury: recommendations on the type and timing of rehabilitation. Global Spine J. 2017;7(3S):231S-238S.

Peer Reviewed Publications

1. 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.
2. Needham-Shropshire BM, Broton JG, Cameron TL, Klose KJ. Improved motor function in tetraplegics following neuromuscular stimulation-assisted arm ergometry. J Spinal Cord Med. 1997;20(1):49-55.
3. Baldi JC, Jackson RD, Moraille R, Mysiw WJ. Muscle atrophy is prevented in patients with acute spinal cord injury using functional electrical stimulation. Spinal Cord. 1998;36(7):463-469.
4. Johnston TE, Smith BT, Mulcahey MJ, Betz RR, Lauer RT. A randomized controlled trial on the effects of cycling with and without electrical stimulation on cardiorespiratory and vascular health in children with spinal cord injury. Arch Phys Med Rehabil. 2009;90(8):1379-1388.
5. 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.
6. 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.
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8. Lai CH, Chang WH, Chan WP, et al. Effects of functional electrical stimulation cycling exercise on bone mineral density loss in the early stages of spinal cord injury. J Rehabil Med. 2010;42(2):150-154.
9. 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.
10. 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.
11. 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.
12. 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.
13. 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.0000000263.
14. Miller L, Rafferty D, Paul L. et al. The impact of walking speed on the effects of functional electrical stimulation for foot drop in people with multiple sclerosis. Disabil Rehabil Assist Technol. 2015 Sep 25:1-6.
15. Hausmann J, Sweeney-Reed CM et al. Functional electrical stimulation through direct 4-channel nerve stimulation to improve gait in multiple sclerosis: a feasibility study. J Neuroeng Rehabil. 2015 Nov 14;12:100. doi: 10.1186/s12984-015-0096-3.
16. Gu P, Ran JJ. Electrical stimulation for hemiplegic shoulder function: A systematic review and meta-analysis of 15 randomized controlled trials. Arch Phys Med Rehabil. 2016 Sep;97(9):1588-94.
17. Knutson JS, Gunzler DD, Wilson RD, Chae J. Contralaterally controlled functional electrical stimulation improves hand dexterity in chronic hemiparesis: A randomized trial. Stroke. 2016 Oct;47(10):2596-602.
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19. Wilson RD, Page SJ, Delahanty M, et al. Upper-limb recovery after stroke: A randomized controlled trial comparing EMG-triggered, cyclic, and sensory electrical stimulation. Neurorehabil Neural Repair. 2016 Nov;30(10):978-87.
20. Prenton S, Hollands KL, Kenney LP. Functional electrical stimulation versus ankle foot orthoses for foot-drop: A meta-analysis of orthotic effects. Journal of rehabilitation medicine. 2016 Oct 5;48(8):646-56.
21. Lee D, Lee G, Jeong J. Mirror therapy with neuromuscular electrical stimulation for improving motor function of stroke survivors: A pilot randomized clinical study. Technology and health care. 2016 Jul 27;24(4):503-11.
22. Awad LN, Reisman DS, Pohlig RT, Binder-Macleod SA. Reducing the cost of transport and increasing walking distance after stroke: A randomized controlled trial on fast locomotor training combined with functional electrical stimulation. Neurorehabil Neural Repair. 2016 Aug;30(7):661-70.
23. de Freitas GR, et al. Does neuromuscular electrical stimulation therapy increase voluntary muscle strength after spinal cord injury? A systematic review. Top Spinal Cord Inj Rehabil. 2018 Winter;24(1):6-17. doi: 10.1310/sci16-00048.
24. Chou RC, Taylor JA, Solinsky R. Effects of hybrid-functional electrical stimulation (FES) rowing whole-body exercise on neurologic improvement in subacute spinal cord injury: Secondary outcomes analysis of a randomized controlled trial. Spinal cord. 2020.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Hayes. Functional electrical stimulation for rehabilitation following spinal cord injury. https://evidence.hayesinc.com. Published November 2017. Updated January 12, 2022. Registration and login required.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Ohio Medicaid: Member must be referred to physical therapy without a mandatory number of visits.