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

Last Approval: 6/14/2023
Next Review Due By: June 2024

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 (SCI), a SCI is an insult to the spinal cord resulting in a change, either temporary or permanent, in its normal motor, sensory, or autonomic function (Marquez-Chin & Popovic 2020; Rapidi et al. 2018). 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 (Karamian et al. 2022; Marquez-Chin & Popovic 2020).
- **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 (Karamian et al. 2022; Marquez-Chin & Popovic 2020).

Functional Electrical Stimulation (FES)

FES is a treatment modality in which electrical impulses are applied to intact peripheral nerves supplying paralyzed muscles 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. 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-months 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 neuromuscular electrical stimulation (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 severe untreated 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 dysreflexia; **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 FES on the general physical fitness and health of patients with 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.

Anderson et al. (2022) completed a multicenter, single-blind, parallel-group, two-arm RCT comparing FES to conventional therapy in adults ≥ 18 years of age with a C4-C7 traumatic SCI with incomplete tetraplegia. Participants were between 4- and 96-months post-injury with a baseline Spinal Cord Independence Measure III - Self-Care (SCIM III-SC) score ≤ 10. Participants were enrolled at 4 SCI-specialized neurorehabilitation centers in the U.S. and Canada. A total of 51 participants were randomized to receive either 40 sessions of FES (27 participants) or 40 sessions of conventional therapy (24 participants) targeting the upper extremities over a 14-week period. Due to the COVID-19

lockdowns, 17 participants required protocol modification to allow those participants to complete the study. The effects of variables related to the pause in protocol remained unknown to the researchers. The primary outcome measured by the RCT was the change in SCIM III-SC scores from baseline to the end of treatment. Blind assessors measured SCIM III-SC, Toronto Rehabilitation Institute Hand Function Test, and Graded Redefined Assessment of Strength, Sensibility, and Prehension at baseline, after the 20th session, after the 40th session or 14 weeks after the first session, and at 24 weeks after the first session. Overall results showed a mean gain of 2 points in SCIM III-SC scores at the end of treatment in both groups.

Karamian et al. (2022) found that FES has shown improvements in various aspects of patients' lives and health. Researchers noted improvements in patient transitions, spasticity, cardiovascular function, and pain. In addition, FES was also noted to provide improvements in upper extremity function. Improvements were also noted in the rehabilitation of lower extremities in conjunction with FES. Improvements in lower extremity function were also noted in gait parameters.

McIntyre et al. (2022) completed a systematic review of evidence-based literature pertaining to pediatric-onset SCI in individuals ≤ 21 years of age. A total of 126 studies from 1974-2020 were included in the review with 66 of those studies evaluating the use of interventions. Pertaining to FES, Researchers found that "FES has been shown to be effective at improving upper extremity movement, efficiency, consistency, and strength." It was also noted that FES showed greater improvement in the performance of skilled tasks as compared to tenodesis.

Van der Scheer et al. (2021) completed a systematic review examining outcomes following FES cycling exercises after SCI. The review included 92 studies with a total of 999 adult patients. Patients were considered an "adult" if they were ≥ 16 years of age. Patients with congenital conditions (e.g., spina bifida) were excluded from the review. "Improvement" for this review was defined as a statistically significant positive change following the intervention in at least one of the outcome measures (muscle health, power output, aerobic fitness, bone health, cardiovascular and metabolic factors, fat mass, muscle strength, other secondary health conditions, subjective well-being, and functional and neurological outcomes). Each study focused on specific outcomes with some overlapping of measured outcomes noted between studies. The GRADE methodology was utilized to assess the certainty of evidence for all included studies. Overall results of the review showed a significant improvement in all outcome measures following FES cycling exercises.

Chou et al. (2020) completed a secondary outcome measures analysis of a RCT to evaluate the effects of a hybrid-FES rowing program on motor and sensory recovery. Included participants were 6-18 months post-SCI. A total of 25 participants were randomized to the experimental group of a hybrid-FES rowing program with 3 scheduled sessions per week for 26 weeks or a standard of care group consisting of 2 arms (arm ergometer exercise program or waitlist without an explicit exercise program). The exercise intensity goal was 70-85% of maximal heart rate goal for each group. Both groups of the RCT demonstrated increases in motor and combined sensory scores with no significant difference noted between intervention groups.

De Freitas et al. (2018) completed a systematic review of 5 studies to determine if electrical stimulation therapy increased voluntary muscle strength following SCI. All studies included in the review included muscle strength as the main outcome measure. Each study measured the maximum voluntary muscle strength using either the manual muscle test (3 studies) or the generation of peak force in newtons (2 studies). Overall results indicated that neuromuscular electrical stimulation may be beneficial in improving muscle strength after SCI.

Rapidi et al. (2018) published an evidence-based position paper for the Physical and Rehabilitation Medicine section of the European Union of Medical Specialists (UEMS). UEMS recommendations for the use of appropriate physical agents (e.g., FES modalities) are that they are "incorporated in the SCI healthcare provision through every stage of recovery, whenever recommended and available." The UEMS rates each recommendation based on the strength of evidence and the strength of recommendation. The UEMS provided a strength of evidence rating of "IV" meaning the rating was backed by "other studies." A UEMS rating of "B" was applied to the strength of recommendation, meaning that recommendation "is important, but can be applied not in all situations."

National and Specialty Organizations

The **National Institute for Health and Care Excellence (NICE)** published guidelines for the use of FES for drop foot of a central neurological origin, including drop foot related to SCI. NICE recommended the use of FES for upper motor neuron lesions (NICE 2012).

The **AO Spine International Board** released guidelines in 2017 for recommendations on the type and timing of rehabilitation. It was recommended that FES be offered to individuals with acute and subacute cervical SCI (Fehlings et al. 2017).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes – None.

HCPCS (Healthcare Common Procedure Coding System) 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

6/14/2023	Policy reviewed. No changes to coverage criteria. Overview, Summary of Medical Evidence, and References sections updated. Supplemental Information section removed. Policy reviewed on May 12, 2023, by a practicing, board-certified physician in the areas of Orthopedic Surgery, Surgery Spine.
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

1. Anderson KD, Korupolu R, Musselman KE, Pierce J, Wilson JR, Yozbatiran N, Desai N, Popovic MR, Thabane L. Multi-center, single-blind randomized controlled trial comparing functional electrical stimulation therapy to conventional therapy in incomplete tetraplegia. Front Rehabil Sci. 2022 Sep 9;3:995244. doi: 10.3389/fresc.2022.995244. PMID: 36188946; PMCID: PMC9500231.
2. Centers for Medicare and Medicaid Services (CMS). National coverage determination (NCD) for neuromuscular electrical stimulation (NMES) (160.12). Effective October 1, 2006. Accessed April 27, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
3. 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 Aug;58(8):914-920. doi: 10.1038/s41393-020-0445-3. Epub 2020 Feb 24. PMID: 32094516; PMCID: PMC7415604.
4. de Freitas GR, Szpoganicz C, Ilha J. 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. Epub 2017 Jun 12. PMID: 29434456; PMCID: PMC5791925.
5. Fehlings MG, Tetreault LA, Aarabi B, Anderson P, Arnold PM, Brodke DS, Chiba K, Dettori JR, Furlan JC, Harrop JS, Hawryluk G, Holly LT, Howley S, Jeji T, Kalsi-Ryan S, Kotter M, Kurpad S, Kwon BK, Marino RJ, Martin AR, Massicotte E, Merli G, Middleton JW, Nakashima H, Nagoshi N, Palmieri K, Singh A, Skelly AC, Tsai EC, Vaccaro A, Wilson JR, Yee A, Burns AS. 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 Sep;7(3 Suppl):231S-238S. doi: 10.1177/2192568217701910. Epub 2017 Sep 5. PMID: 29164029; PMCID: PMC5684839.

6. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). P900038: Parastep-I. Published April 20, 1994. Accessed April 27, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P900038.
7. Hayes. Functional electrical stimulation for rehabilitation following spinal cord injury. Published November 2017. Updated January 12, 2022. Archived December 16, 2022, Accessed April 27, 2023. https://evidence.hayesinc.com.
8. Karamian BA, Siegel N, Nourie B, Serruya MD, Heary RF, Harrop JS, Vaccaro AR. The role of electrical stimulation for rehabilitation and regeneration after spinal cord injury. J Orthop Traumatol. 2022 Jan 6;23(1):2. doi: 10.1186/s10195-021-00623-6. PMID: 34989884; PMCID: PMC8738840.
9. Marquez-Chin C, Popovic MR. Functional electrical stimulation therapy for restoration of motor function after spinal cord injury and stroke: a review. Biomed Eng Online. 2020 May 24;19(1):34. doi: 10.1186/s12938-020-00773-4. PMID: 32448143; PMCID: PMC7245767.
10. McIntyre A, Sadowsky C, Behrman A, Martin R, Augutis M, Cassidy C, Betz R, Ertzgaard P, Mulcahey MJ; SCIRE Project Research Group. A Systematic Review of the Scientific Literature for Rehabilitation/Habilitation Among Individuals With Pediatric-Onset Spinal Cord Injury. Top Spinal Cord Inj Rehabil. 2022 Spring;28(2):13-90. doi: 10.46292/sci21-00046. Epub 2022 Apr 12. PMID: 35521053; PMCID: PMC9009193.
11. National Institute for Health Care and Excellence (NICE). Guidance IPG278: Functional electrical stimulation for drop foot of central neurological origin. Published January 2009. Updated 2012. Accessed May 9, 2023. https://www.nice.org.uk/guidance/ipg278.
12. Rapidi CA, Tederko P, Moslavac S, Popa D, Branco CA, Kiekens C, Varela Donoso E, Christodoulou N; Professional Practice Committee of the UEMS-PRM Section. Evidence-based position paper on Physical and Rehabilitation Medicine (PRM) professional practice for persons with spinal cord injury. The European PRM position (UEMS PRM Section). Eur J Phys Rehabil Med. 2018 Oct;54(5):797-807. doi: 10.23736/S1973-9087.18.05374-1. Epub 2018 Jun 27. PMID: 29952157.
13. van der Scheer JW, Goosey-Tolfrey VL, Valentino SE, Davis GM, Ho CH. Functional electrical stimulation cycling exercise after spinal cord injury: a systematic review of health and fitness-related outcomes. J Neuroeng Rehabil. 2021 Jun 12;18(1):99. doi: 10.1186/s12984-021-00882-8. PMID: 34118958; PMCID: PMC8196442.