Molina Clinical Policy
Functional Electrical Stimulation for Spinal Cord Injury
Policy No. 205

Last Approval: 06/11/2025
Next Review Due By: June 2026

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), SCI is defined as damage to the spinal cord that results in a disruption, either temporary or permanent, of normal motor, sensory, or autonomic function (Marquez-Chin & Popovic 2020; Rapidi et al. 2018). Spinal cord injuries are categorized primarily into two types:

- **Tetraplegia** refers to the partial or complete loss of motor and/or sensory function in the cervical spinal cord segments due to damage within the neural canal. This impairment affects the arms and typically extends to the trunk, legs and pelvic organs, involving all four extremities. Tetraplegia excludes injuries such as brachial plexus lesions or peripheral nerve damage outside the spinal canal (Karamian et al. 2022; Marquez-Chin & Popovic 2020).
- **Paraplegia** refers to the impairment or loss of motor and/or sensory function in the thoracic, lumbar, or sacral spinal cord segments- excluding the cervical region. In paraplegia, arm function is preserved, but the trunk, legs, and pelvic organs may be affected depending on the level of the lesion. This term encompasses injuries to the cauda equina and conus medullaris injuries but not lesions of the lumbosacral plexus or peripheral nerves outside the neural canal (Karamian et al. 2022; Marquez-Chin & Popovic 2020).

Functional Electrical Stimulation (FES) is a rehabilitative therapy used to produce functional movement in individuals with paralysis by delivering electrical impulses to intact peripheral nerves that innervate affected muscles. These impulses stimulate muscle contractions, aiding in the restoration or improvement of motor function. FES systems generally include a stimulator that generates the electrical pulses, electrodes that deliver those pulses to the appropriate sites, lead wires connecting the stimulator to the electrodes, and a control unit that supplies power and operational commands. There are three primary types of FES systems: surface (transcutaneous), percutaneous, and fully implanted. Surface systems utilize electrodes placed on the skin and an external control unit worn on the body. Percutaneous systems involve implanted electrodes with lead wires that exit the skin and connect to an external stimulator. Fully implanted systems house the electrodes, lead wires, and stimulator beneath the skin, receiving power and programming instructions via radio-frequency telemetry from an external unit. Electrodes may be positioned on the surface of a muscle, inserted within the muscle, or placed near a motor nerve. Regardless of placement, they are targeted to the motor point of each muscle – the location where stimulation produces the most efficient and isolated contraction with the least amount of electrical current (Hayes 2022).

FES cycling and other FES-assisted exercise devices are commonly used in clinical and home settings to promote cardiovascular health, muscle strength, and neuroplasticity in individuals with SCI. These devices combine electrical stimulation with functional movement such as cycling, rowing, or stepping to support active rehabilitation and improved quality of life.

Regulatory Status

The U.S. Food and Drug Administration (FDA) granted premarket approval (PMA No. P900038) for the Parastep I system (Sigmedics, Inc.) on April 20, 1994. This device, intended for use in individuals with tetraplegia, was classified as a Class III medical device (FDA 1994).

COVERAGE POLICY

Functional Electrical Stimulation may be **considered medically necessary** for Members with a spinal cord injury for walking rehabilitation when ALL the following are met:

1. The system is used as part of a comprehensive rehabilitation program including ALL the following:
   a. Completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months
   b. Training must be directly performed by the physical therapists as part of a one-on-one training program

2. Member is at least 6-months post recovery spinal cord injury and restorative surgery

3. Member has intact lower motor units of both muscle and peripheral nerves at L1 and below

4. 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

5. Absence of ALL the following contraindications:
   a. Severe untreated hip and knee degenerative disease
   b. History of long bone fracture secondary to severe osteoporosis
   c. Presence of cardiac pacemakers
   d. Severe scoliosis
   e. Skin disease or cancer at area of stimulation
   f. Severe irreversible muscle spasticity/contractures
   g. Poorly controlled epilepsy
   h. Fracture or dislocation near or on the site of application
   i. Autonomic dysreflexia

6. Member can demonstrate ALL the following:
   a. Brisk muscle contraction to neuromuscular electrical stimulation
   b. Sensory perception to electrical stimulation sufficient for muscle contraction
   c. Hand and finger function to manipulate controls
   d. Independent transfer
   e. Independent standing tolerance for at least 3 minutes
   f. Cognitive ability to use devices for walking

7. Documented evidence of Member motivation and compliance with device use, and attestation of Member willingness to use device long term

Limitations and Exclusions

Functional Electrical Stimulation Exercise Devices (e.g., FES Power Trainer, RT300 FES Cycle Ergometer, RT200 Elliptical, RT600 Step and Stand Rehabilitation Therapy System, RehaMove FES, Myocycle, ERGYS, REGYS, NeuroEDUCATOR, STimMaster Galaxy, and SpectraSTIM etc.) are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes. This list is not exhaustive; additional devices with similar functions or mechanisms are included under this classification.

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

Current evidence regarding the effects of Functional Electrical Stimulation (FES) on the overall physical health and fitness in individuals with Spinal Cord Injury (SCI) includes small randomized controlled trials (RCTs), prospective trials, and systematic reviews. These studies outline the effectiveness of FES in improving various functional outcomes, including mobility and gait, in patients with incomplete SCI.

Randomized Controlled Trials
Anderson et al. (2022) completed a multicenter, single-blind, parallel-group RCT evaluating FES compared to conventional therapy in adults ≥ 18 years of age with traumatic incomplete tetraplegia (C4-C7). Participants were between 4- and 96-months post-injury and had baseline Spinal Cord Independence Measure III - Self-Care (SCIM III-SC) score ≤ 10. The trial enrolled 51 participants across four specialized SCI neurorehabilitation centers in the U.S. and Canada. Participants were randomized to receive 40 sessions of FES (n = 27) or 40 sessions of conventional upper extremity therapy (n = 24) over a 14-week period. Due to the COVID-19 pandemic, 17 participants required underwent protocol modifications, potentially influencing outcomes, though the exact impact was not fully understood. The primary outcome measured was the change in SCIM III-SC scores from baseline to the end of treatment. Additional outcomes included the Toronto Rehabilitation Institute Hand Function Test, and Graded Redefined Assessment of Strength, Sensibility, and Prehension. These were assessed at baseline, mid-intervention (20 sessions), post-intervention (40 sessions or week 14), and at a 24-week follow-up. Results indicated a modest mean improvement of 2 points in SCIM III-SC scores in both the FES and control groups.

Fornusek et al. (2012) performed a randomized controlled trial to examine how different cycling cadences during FES training affect leg muscle growth and electrically induced quadriceps strength in individuals with SCI. Eight participants trained three times per week for six weeks, with one leg assigned to low cadence (10 rpm) and the other to high cadence (50 rpm). Both conditions led to significant increases in thigh circumference and quadriceps torque; however, the low-cadence leg showed greater improvements—especially in muscle growth (up to 6.6%) and torque (87% increase vs. 20%). Cycling performance also improved across both cadences, though higher crank torque was observed in the low-cadence group. Despite promising results, limitations such as a small sample size and lack of statistical corrections suggest that findings should be interpreted with caution. These results support the potential benefit of low-cadence FES cycling for enhancing strength and muscle mass in individuals with SCI, though further research is needed.

Systematic Reviews and Meta-Analyses
Alashram et al. (2022) conducted a systematic review of 10 studies assessing the impact of FES cycling on lower extremity spasticity in individuals with SCI. Primary outcome measures included spasticity assessments using tools such as the Modified Ashworth Scale (MAS), Pendulum Test, Numerical Rating Scale for Spasticity (NRS-spasticity), and Patient-Reported Impact of Spasticity Measure (PRISM). The review found significant reductions in MAS and NRS-spasticity scores in several studies post-treatment and at 3- and 6-month follow-ups ($p < 0.05$). One study showed improvements in MAS and Pendulum scores following FES cycling compared to controls ($p < 0.05$), while another observed within-group improvements without statistically significant differences between groups. Some studies reported no significant changes in MAS or PRISM scores ($p > 0.05$). Limitations included small sample sizes, variability in study design, and exclusion of non-English-language publications. Due to heterogeneity, meta-analysis was not feasible. The review provided evidence for the support of FES cycling as a beneficial therapy for reducing lower extremity spasticity in individuals with SCI.

Van der Scheer et al. (2021) published a systematic review of 92 studies involving 999 adult participants (≥ 16 years of age) with SCI, excluding those with congenital conditions such as spina bifida. The review assessed the effects of FES cycling on a range of outcomes including muscle health, power output, aerobic fitness, bone health, cardiovascular/metabolic factors, fat mass, muscle strength, secondary health conditions, subjective well-being, and neurological function. Outcomes were considered improved if studies demonstrated statistically significant positive changes post-intervention. The GRADE method was used to evaluate the certainty of evidence. Overall, the review found consistent improvements across most outcome categories following FES cycling interventions.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Chou et al. (2020) performed a secondary analysis of an RCT to examine the effects of a hybrid FES-rowing program on motor and sensory function. Participants, 6 to 18 months post-SCI, were randomized to either a hybrid FES rowing group (three sessions per week for 26 weeks) or a control group (arm ergometer or waitlist). All interventions targeted a training intensity of 70-85% of the participant's maximum heart rate. Both the FES and control groups demonstrated improvements in motor and combined sensory scores, though no significant differences were observed between the groups. The findings suggest that both interventions may support neurological recovery, but FES rowing did not show a clear advantage over traditional modalities.

National and Specialty Organizations

The **National Institute for Health and Care Excellence (NICE)** published guidelines supporting the use of FES for drop foot resulting from central neurological conditions, including SCI. The recommendation applies specifically to upper motor neuron lesions (NICE 2012).

The **AO Spine International Board** provided recommendations for SCI rehabilitation, endorsing the use of FES in individuals with acute and subacute cervical SCI to support functional recovery (Fehlings et al. 2017).

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	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

06/11/2025	Policy reviewed. Updated coverage criteria to include E/I/U statement for functional electrical stimulation exercise devices. Updated Summary of Medical Evidence and References. IRO Peer Review on April 30, 2025, by a practicing physician board-certified in Orthopedic Surgery, Surgery Spine.
06/12/2024	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
06/14/2023	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.
06/08/2022	Policy reviewed, no changes.
06/09/2021	Policy reviewed, no changes.
06/17/2020	Policy reviewed, no changes.
06/19/2019	Policy reviewed. Inclusion of Parastep I System for spinal cord injury for ease of application; references updated.
07/10/2018	Policy reviewed, no changes. Updated professional guidelines.
08/23/2017	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.
09/15/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
08/27/2014	New policy.

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