Functional Neuromuscular Electrical Stimulation

Policy # 00042
Original Effective Date: 05/12/2003
Current Effective Date: 08/14/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers neuromuscular stimulation as a technique to restore function following nerve damage or nerve injury to be investigational.*

This includes its use in the following situations:
- As a technique to provide ambulation in individuals with spinal cord injury; OR
- To provide upper extremity function in individuals with nerve damage (e.g., spinal cord injury or post-stroke); OR
- To improve ambulation in individuals with foot drop caused by congenital disorders (e.g. cerebral palsy) or nerve damage (e.g., post stroke, or in those with multiple sclerosis [MS]).

Based on review of available data, the Company considers functional electrical stimulation (FES) devices for exercise in individuals with spinal cord injury to be investigational.*

Background/Overview
Functional Electrical Stimulation
Functional electrical stimulation is an approach to rehabilitation that applies low-level electrical current to stimulate functional movements in muscles affected by nerve damage. It focuses on the restoration of useful movements, like standing, stepping, pedaling for exercise, reaching, or grasping.

Functional electrical stimulation devices consist of an orthotic and a microprocessor-based electronic stimulator with 1 or more channels for delivery of individual pulses through surface or implanted electrodes connected to the neuromuscular system. Microprocessor programs activate the channels sequentially or in unison to stimulate peripheral nerves and trigger muscle contractions to produce

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Functionally useful movements that allow patients to sit, stand, walk, cycle, or grasp. Functional neuromuscular stimulators are closed-loop systems that provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities (eg, walking). These systems are contrasted with open-loop systems, which are used for simple tasks (eg, muscle strengthening alone); healthy individuals with intact neural control benefit the most from this technology.

Applications, described in more detail in the Rationale section, include upper-extremity grasping function after spinal cord injury (SCI) and stroke; lifting the front of the foot during ambulation in individuals with foot drop; and ambulation and exercise for patients with SCI. Some devices are used primarily for rehabilitation rather than home use. This evidence review focuses on devices intended for home use.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
A variety of FES devices have been cleared by the U.S. FDA and are available for home use. Table 1 provides examples of devices designed to improve hand and foot function as well as cycle ergometers for home exercise. The date of the FDA clearance is for the first 510(k) clearance identified for a marketed device. Many devices have additional FDA clearances as the technology evolved, each in turn listing the most recent device as the predicate.

Table 1. Functional Electrical Stimulation Devices Cleared by the FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Device Type</th>
<th>Clearance</th>
<th>Date</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>NESS H200®‡</td>
<td>Bioness</td>
<td>Hand stimulator</td>
<td>K022776</td>
<td>2001</td>
<td>GZI</td>
</tr>
<tr>
<td>(previously Handmaster)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MyndMove System</td>
<td>MyndTec</td>
<td>Hand stimulator</td>
<td>K170564</td>
<td>2017</td>
<td>GZI/IPF</td>
</tr>
<tr>
<td>ReGrasp</td>
<td>Rehabtronics</td>
<td>Hand stimulator</td>
<td>K153163</td>
<td>2016</td>
<td>GZI/IPF</td>
</tr>
<tr>
<td>Product</td>
<td>Manufacturer/Company</td>
<td>Equipment Type</td>
<td>K-Number</td>
<td>Year</td>
<td>Code</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------------------------------------------</td>
<td>-------------------------</td>
<td>--------------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>WalkAide®‡ System</td>
<td>Innovative Neurotronics (formerly NeuroMotion)</td>
<td>Foot drop stimulator</td>
<td>K052329</td>
<td>2005</td>
<td>GZI</td>
</tr>
<tr>
<td>ODFS®‡ (Odstock Dropped Foot Stimulator)</td>
<td>Odstock Medical</td>
<td>Foot drop stimulator</td>
<td>K050991</td>
<td>2005</td>
<td>GZI</td>
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<tr>
<td>ODFS®‡ Pace XL</td>
<td>Odstock Medical</td>
<td>Foot drop stimulator</td>
<td>K171396</td>
<td>2018</td>
<td>GZI/IPF</td>
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<tr>
<td>L300 Go</td>
<td>Bioness</td>
<td>Foot drop stimulator</td>
<td>K190285</td>
<td>2019</td>
<td>GZI/IPF</td>
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<tr>
<td>L100 Go</td>
<td>Bioness</td>
<td>Foot drop stimulator</td>
<td>K200262</td>
<td>2020</td>
<td>GZI/IPF</td>
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<tr>
<td>Foot Drop System</td>
<td>SHENZHEN XFT Medical</td>
<td>Foot drop stimulator</td>
<td>K162718</td>
<td>2017</td>
<td>GZI</td>
</tr>
<tr>
<td>Nerve And Muscle Stimulator</td>
<td>SHENZHEN XFT Medical</td>
<td>Foot drop stimulator</td>
<td>K193276</td>
<td>2020</td>
<td>GZI</td>
</tr>
<tr>
<td>MyGait®‡ Stimulation System</td>
<td>Otto Bock HealthCare</td>
<td>Foot drop stimulator</td>
<td>K141812</td>
<td>2015</td>
<td>GZI</td>
</tr>
<tr>
<td>MSStim Drop Model LGT-233</td>
<td>Guangzhou Longest Science &amp; Technology</td>
<td>Foot drop stimulator</td>
<td>K202110</td>
<td>2021</td>
<td>GZI/IPF</td>
</tr>
<tr>
<td>ERGYS (TTI Rehabilitation Gym)</td>
<td>Therapeutic Alliances</td>
<td>Leg cycle ergometer</td>
<td>K841112</td>
<td>1984</td>
<td>IPF</td>
</tr>
<tr>
<td>RT300</td>
<td>Restorative Therapies, Inc (RTI)</td>
<td>Cycle ergometer</td>
<td>K050036</td>
<td>2005</td>
<td>GZI</td>
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<tr>
<td>Myocycle Home</td>
<td>Myolyn</td>
<td>Cycle ergometer</td>
<td>K170132</td>
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<td>GZI</td>
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To date, the Parastep® Ambulation System (Sigmedics) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the FDA. The Parastep device is approved to “enable appropriately selected skeletally mature spinal cord injured patients (level C6 to T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury.” FDA product code: MKD.

**Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Functional electrical stimulation involves the use of an orthotic device or exercise equipment with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function and improve health in patients with damaged or destroyed nerve pathways (eg, SCI, stroke, multiple sclerosis, cerebral palsy).

**Summary of Evidence**

For individuals who have loss of hand and upper-extremity function due to SCI or stroke who receive FES, the evidence includes a few small case series and a randomized controlled trial (RCT). Relevant outcomes are functional outcomes and quality of life. Interpretation of the evidence is limited by the low number of patients studied and lack of data demonstrating the utility of FES outside the investigational setting. It is uncertain whether FES can restore some upper-extremity function or improve the quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
For individuals who have chronic foot drop who receive FES, the evidence includes RCTs, meta-analyses, and a longitudinal cohort study. Relevant outcomes are functional outcomes and quality of life. For chronic poststroke foot drop, 2 RCTs comparing FES with a standard ankle-foot orthosis (AFO) showed improved patient satisfaction with FES but no significant differences between groups in objective measures such as walking. Another RCT found no significant differences between use versus no use of FES on walking outcomes. Similarly, one meta-analysis found no difference between AFO and FES in walking speed, and another meta-analysis found no difference between FES and conventional treatments. The cohort study assessed patients’ ability to avoid obstacles while walking on a treadmill using FES versus AFO. Although the FES group averaged a 4.7% higher rate of avoidance, the individual results between devices ranged widely. One RCT with 53 subjects examining neuromuscular stimulation for foot drop in patients with multiple sclerosis showed a reduction in falls and improved patient satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. Another RCT showed that at 12 months, both FES and AFO had improved walking speed, but the difference in improvement between the 2 devices was not significant. Another study found FES (combined with postural correction) and neuroproprioceptive facilitation and inhibition physiotherapy did not differ in walking speed or balance immediately or 2 months after program end. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be corroborated. The literature on FES in children with cerebral palsy includes 3 systematic reviews of small studies with within-subject designs. All included studies only measure short-term results; it is unclear what the long-term effects of FES may be in this population. Further study is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI at segments T4 to T12 who receive FES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. No controlled trials were identified on FES for standing and walking in patients with SCI. However, case series are considered adequate for this condition because there is no chance for unaided ambulation in this population with SCI at this level. Some studies have reported improvements in intermediate outcomes, but improvements in health outcomes (eg, ability to perform activities of daily living [ADL], quality of life) have not been demonstrated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI who receive FES exercise equipment, the evidence includes prospective comparisons. Relevant outcomes are symptoms, functional outcomes, and quality of life.
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The evidence on FES exercise equipment consists primarily of within-subject, pretreatment to posttreatment comparisons. Evidence was identified on 2 commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is limited evidence on the RT300 series. None of the within-subject studies showed an improvement in health benefits; however, improvement in body fat with RT300 was found in a small group of patients when FES high intensity interval cycling was added to nutrition counseling compared to nutritional counseling alone. One analysis of use for 314 individuals over 20,000 activity sessions with a Restorative Therapies device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of 6 days per week, but caloric expenditure remained low. Compliance was shown in 1 study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function; however, a small comparative study found arm cycling to improve exercise energy expenditure and cardiorespiratory fitness to a greater extent than FES leg cycling. A limitation of these studies is that they all appear to have been conducted in supervised research centers. No studies were identified on long-term home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information
Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence
In 2009, NICE published guidance stating that the evidence on functional electrical stimulation for foot drop of neurologic origin appeared adequate to support its use. The Institute noted that patient selection should involve a multidisciplinary team. The Institute advised that further publication on the efficacy of functional electrical stimulation would be useful, specifically including patient-
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reported outcomes (eg, quality of life, activities of daily living [ADL]) and these outcomes should be examined in different ethnic and socioeconomic groups.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Medicare (2002; updated in 2006) issued a national coverage policy recommending coverage for neuromuscular electrical stimulation for ambulation in spinal cord injury patients consistent with the U.S. FDA labeling for the Parastep device. The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in its decision-making process. The decision memorandum noted that the available studies were flawed but concluded that the limited ambulation provided by the Parastep device supported its clinical effectiveness and thus its coverage eligibility. The inclusion criteria outlined by Medicare are as follows:

- "Persons with intact lower motor units (L1 and below);
- 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;
- Persons who demonstrate brisk muscle contraction to NMES [neuromuscular electrical stimulation] and have sensory perception of electrical stimulation sufficient for muscle contraction;
- Persons that possess high motivation, commitment, and cognitive ability to use such devices for walking;
- Persons that can transfer independently and can demonstrate standing tolerance for at least 3 minutes;
- Persons that can demonstrate hand and finger function to manipulate controls;
- Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
- Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
- Persons that have demonstrated a willingness to use the device long-term."

The exclusion criteria are as follows:

- "Persons with cardiac pacemakers;
- Severe scoliosis or severe osteoporosis;

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Skin disease or cancer at area of stimulation;
- Irreversible contracture; or
- Autonomic dysreflexia."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT03949387</td>
<td>Functional Electrical Stimulation Cycling for Managing Mobility Disability in People With Multiple Sclerosis</td>
<td>40</td>
<td>Dec 2023</td>
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<tr>
<td>NCT03410498</td>
<td>The Orthotic Effect of Functional Electrical Stimulation to Treat Foot Drop in People With MS Under Walking Conditions Simulating Those in Daily Life</td>
<td>20</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT04945395</td>
<td>The Effect of Using Functional Electric Stimulation for the Recovery of Dorsiflexion During Rehabilitation of Gait Function, in the Subacute Phase After Stroke- a Randomized Controlled Exploratory Study</td>
<td>20</td>
<td>Dec 2023</td>
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<tr>
<td>NCT03385005</td>
<td>Evaluating Neuromuscular Stimulation for Restoring Hand Movements</td>
<td>8</td>
<td>Jun 2023</td>
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<tr>
<td>NCT03495986</td>
<td>Spinal Cord Injury Exercise and Nutrition Conceptual Engagement (SCIENCE)</td>
<td>60</td>
<td>May 2023</td>
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<tr>
<td>NCT00583804</td>
<td>Implanted Myoelectric Control for Restoration of Hand Function in Spinal Cord Injury</td>
<td>10</td>
<td>Jan 2026</td>
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<table>
<thead>
<tr>
<th>Unpublished</th>
<th>NCT00890916</th>
<th>Hand Function for Tetraplegia Using a Wireless Neuroprosthesis</th>
<th>10</th>
<th>May 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT03440632</td>
<td>Functional Electrical Stimulation of the Ankle Dorsiflexors During Walking in Children With Unilateral Spastic Cerebral Palsy: a Randomized Crossover Intervention Study</td>
<td>25</td>
<td>Sept 2021</td>
<td></td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

References

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41. Johnston TE, Smith BT, Mulcahey MJ, et al. A randomized controlled trial on the effects of cycling with and without electrical stimulation on cardiorespiratory and vascular health in
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Policy History
Original Effective Date: 05/12/2003
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04/25/2003 Medical Policy Committee review
05/12/2003 Managed Care Advisory Council approval
05/03/2005 Medical Director review

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05/23/2005 Managed Care Advisory Council approval
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/01/2007 Medical Director review
08/06/2009 Medical Policy Committee approval.
08/05/2010 Medical Policy Committee approval.
08/18/2010 Medical Policy Implementation Committee approval. Title changed to Functional Neuromuscular Electrical Stimulation. Additional investigational statements added.
10/01/2010 Coding revision only
08/04/2011 Medical Policy Committee approval.
08/17/2011 Medical Policy Implementation Committee approval. No change to coverage.
08/02/2012 Medical Policy Committee review
08/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2013 Medical Policy Committee review
08/21/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2014 Medical Policy Committee review
08/20/2014 Medical Policy Implementation Committee approval. Cerebral palsy added to investigational statement.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015 Medical Policy Committee review
12/01/2016 Medical Policy Committee review

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01/01/2017  Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017  Medical Policy Committee review
12/20/2017  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018  Medical Policy Committee review
12/19/2018  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/05/2019  Medical Policy Committee review
12/11/2019  Medical Policy Implementation Committee approval. Coverage changes with the review of functional electrical stimulation exercise equipment added to policy; this is considered investigational.
07/02/2020  Medical Policy Committee review
07/08/2020  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021  Medical Policy Committee review
07/14/2021  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/07/2022  Medical Policy Committee review
07/13/2022  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/06/2023  Medical Policy Committee review
07/12/2023  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date:  07/2024

**Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<th>Code Type</th>
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<td>CPT</td>
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<tr>
<td>HCPCS</td>
<td>C1883, E0764, E0770</td>
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<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety,
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effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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