MEDICAL POLICY – 8.03.01

Functional Neuromuscular Electrical Stimulation

BCBSA Ref. Policy: 8.03.01*

Introduction

To move a muscle, the brain sends an electrical signal. The signal travels along the nerve to the muscle fibers. When the muscle fibers receive the signal, they move. Instead of the electrical signals coming from the brain, functional neuromuscular electrical stimulation sends electricity to the muscles through an external power source. The signals arise from a microprocessor and flow to electrodes that are placed on the skin with a patch or implanted. The electrical signals stimulate the targeted nerves to create muscle contractions. This technique has been proposed as a way to try to bring back muscle function after illness, injury, or surgery. It has also been proposed to strengthen muscles that haven’t been used for some time. There is not enough evidence in the medical studies published to date to show how well this proposed treatment works. For this reason, it’s considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

**Procedure**

**Investigational**

Neuromuscular stimulation

Neuromuscular stimulation is considered investigational as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations:

- As a technique to provide ambulation in patients with spinal cord injury
- To provide upper extremity function in patients with nerve damage (eg, spinal cord injury or post-stroke)
- To improve ambulation in patients with foot-drop caused by congenital disorders (eg, cerebral palsy) or nerve damage (eg, post-stroke or in those with multiple sclerosis)

**Coding**

**Code**

**Description**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0764</td>
<td>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 (such as the ParaStep® - an ambulation aid for patients with spinal cord injury)</td>
</tr>
<tr>
<td>E0770</td>
<td>Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (such as stimulators used in patients with footdrop)</td>
</tr>
</tbody>
</table>

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Related Information
Benefit Application

This policy does not refer to commercially available exercycles that use electrical muscle stimulation technology as a means of physical therapy and exercise for patients with spinal cord injury such as the RT300 motorized functional electrical stimulator (FES) Cycle Therapy System. These exercycles are sometimes called functional neuromuscular exercisers. The goals for using these devices may be to promote cardiovascular conditioning, prevent muscle atrophy, and/or maintain bone mass. The patient's legs are wrapped in fabric strips that contain electrodes to stimulate the muscles, thus permitting the patient to pedal.

FES devices including but not limited to the following are considered home exercise equipment: ERGYS (leg cycle ergometer, REGYS (leg cycle RT200 Elliptical, RT300 RES cycle ergometer (also referred to as FES bicycle), StimMaster Galaxy (FES exercise bike) or the RT600 Step and Stand Rehabilitation Therapy System for stationary exercise.

The Company considers FES devices to be physical therapy exercise equipment. Most contract plans exclude coverage of exercise equipment for use in the home. Please refer to the member’s contract language for details.

Evidence Review

Description

Functional neuromuscular electrical stimulation (NMES) involves the use of an orthotic device with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function to patients with damaged or destroyed nerve pathways (eg, spinal cord injury (SCI), stroke, multiple sclerosis, cerebral palsy).

Background

Functional neuromuscular electrical stimulation (NMES) 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 NMES devices consist of an orthotic and a microprocessor-based electronic stimulator with one 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 functionally useful movements that allow patients to sit, stand, walk, and 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 (e.g., walking). These systems are contrasted with open-loop systems, which are used for simple tasks (e.g., muscle strengthening alone); healthy individuals with intact neural control benefit the most from this technology.

**Summary of Evidence**

For individuals who have loss of hand function due to spinal cord injury or stroke who receive functional neuromuscular electrical stimulation (NMES), the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. Evidence on functional NMES for the upper limb in patients with spinal cord injury or stroke includes a few small case series. Interpretation of the evidence is limited by the small number of patients studied and lack of data demonstrating the utility of NMES outside the investigational setting. It is uncertain whether NMES can restore some upper-extremity function or improve quality of life. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic footdrop who receive functional NMES, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are functional outcomes and quality of life. For chronic poststroke footdrop, 2 large RCTs have shown improved patient satisfaction with NMES, however, in objective measures (e.g., walking) no significant difference has been observed between NMES and a standard ankle-foot orthosis. A small randomized trial examining neuromuscular stimulation for footdrop in patients with multiple sclerosis revealed a clinically significant reduction in falls, the trial also revealed an improvement in patient satisfaction with the neuromuscular stimulation (as opposed to an exercise program). However, in the area of walking speed, the trial failed to demonstrate a clinically significant benefit to the neuromuscular stimulation over an exercise class. Studies in a larger number of patients are needed to provide greater certainty about the generalizability of this health outcome. The literature on NMES for footdrop in children with cerebral palsy includes a systematic review of small studies within-subject designs; additional study in a larger number of subjects is needed. Overall, there is insufficient evidence for some indications, and a lack of improvement in
objective measures for others. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT03385005</td>
<td>Evaluating Neuromuscular Stimulation for Restoring Hand Movements</td>
<td>15</td>
<td>Mar 2018</td>
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<tr>
<td>NCT00583804</td>
<td>Implanted Myoelectric Control for Restoration of Hand Function in Spinal Cord Injury</td>
<td>50</td>
<td>Jan 2019</td>
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<tr>
<td>NCT02602639</td>
<td>Functional Electrical Stimulation with Rowing as Exercise after Spinal Cord Injury (FES)</td>
<td>6</td>
<td>Sep 2019</td>
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<tr>
<td>NCT02821884</td>
<td>Combine Transcranial Direct Current Stimulation and Neuromuscular Electrical Stimulation on Stroke Patients</td>
<td>90</td>
<td>Dec 2019</td>
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<tr>
<td>NCT03379532</td>
<td>Brain Computer Interface-Controlled NMES in Subacute Stroke</td>
<td>32</td>
<td>Dec 2020</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT00890916</td>
<td>Hand Function for Tetraplegia Using a Wireless Neuroprosthesis</td>
<td>11</td>
<td>Dec 2017</td>
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</table>
Practice Guidelines and Position Statements

**National Institute for Health and Clinical Excellence (NICE)**

In 2009, the National Institute for Health and Care Excellence published guidance stating that the evidence on functional electrical stimulation for footdrop 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-reported outcomes (e.g., quality of life, activities of daily living) and these outcomes should be examined in different ethnic and socioeconomic groups.

**Medicare National Coverage**

In 2002 (updated in 2006), Medicare issued a national coverage policy recommending coverage for NMES for ambulation in spinal cord injury patients consistent with the Food and Drug Administration labeling for the Parastep device. The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in their decision-making process. The decision memorandum notes 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 and exclusion criteria outlined by Medicare are as follows:

**Inclusion Criteria**

1. Persons with intact lower motor units (L1 and below)

2. 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

3. Persons who demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction
4. Persons who possess high motivation, commitment, and cognitive ability to use such devices for walking

5. Persons who can transfer independently and can demonstrate standing tolerance for at least 3 minutes

6. Persons who can demonstrate hand and finger function to manipulate control

7. Persons with at least 6-month post recovery spinal cord injury and restorative surgery

8. Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis

9. Persons who have demonstrated a willingness to use the device long-term

**Exclusion Criteria**

1. Persons with cardiac pacemakers

2. Severe scoliosis or severe osteoporosis

3. Skin disease or cancer at area of stimulation

4. Irreversible contracture

5. Autonomic dysreflexia

**Regulatory Status**

In 1997, the Freehand® System was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The implantable Freehand® System is no longer marketed in the United States. The Handmaster NMS I system (now named NESS H200®) was originally cleared for marketing by FDA through the 510(k) process for maintaining or improving range of motion, reducing muscle spasm, preventing or retarding muscle atrophy, providing muscle re-education, and improving circulation (K022776); in 2001, its 510(k) marketing clearance was expanded to include provision of hand active range of motion and function for patients with C5 tetraplegia. FDA product code: GZC.

The WalkAide® System (Innovative Neurotronics, Gainesville, FL; formerly NeuroMotion) was first cleared for marketing by FDA through the 510(k) process in the 1990s (K052329); the
current version of the WalkAide® device received 510(k) marketing clearance in 2005. The ODFS® (Odstock Dropped Foot Stimulator; Odstock Medical, Salisbury, U.K.) received 510(k) marketing clearance in 2005 (K050991). The NESS L300® (Bioness, Valencia, CA) was cleared for marketing by FDA through the 510(k) process in 2006. In 2015, the MyGait® Stimulation System (Otto Bock HealthCare, Duderstadt, Germany) received 510(k) marketing clearance (K141812). FDA summaries of the devices state that they are intended for patients with footdrop and assist with ankle dorsiflexion during the swing phase of gait. FDA product code: GZI.

To date, the Parastep® Ambulation System (Sigmedics, Northfield, IL) 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-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.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>01/97</td>
<td>Add to Therapy Section - New Policy</td>
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<tr>
<td>06/27/00</td>
<td>Replace Policy - Policy revised to focus on ambulation.</td>
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<tr>
<td>05/13/03</td>
<td>Replace Policy - Literature review update; added to Rationale/Source section; No change in policy statement.</td>
</tr>
<tr>
<td>06/08/04</td>
<td>Replace Policy - Policy updated; no change in policy statement.</td>
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<tr>
<td>08/09/05</td>
<td>Replace Policy - Policy reviewed with literature search; no new clinical trials found. Policy statement unchanged.</td>
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<td>02/06/06</td>
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<td>06/23/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
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<tr>
<td>12/11/07</td>
<td>Replace Policy - Policy updated with literature review; policy statement clarified to include: “ambulation in patients with spinal cord injury and post-stroke” as investigational. References added.</td>
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<tr>
<td>06/09/09</td>
<td>Replace Policy - Policy updated with literature search. Policy statements modified to add a second policy statement that use of these devices in post-stroke patients is considered investigational. References added.</td>
</tr>
<tr>
<td>10/13/09</td>
<td>Replace Policy - Policy extensively updated with literature search. Additional applications added to policy statement (hand and foot). Title updated to Functional neuromuscular electrical stimulation. References updated.</td>
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<tr>
<td>03/08/11</td>
<td>Replace Policy - Policy updated with literature review; references added and reordered. Policy statement remains unchanged.</td>
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<tr>
<td>04/25/12</td>
<td>Replace policy. Policy updated with literature review through December 2011; reference 25 added; policy statement unchanged.</td>
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<td>Comments</td>
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<td>10/09/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<td>04/08/13</td>
<td>Replace policy. Policy updated with literature review through January 16, 2013; references 11-12 and 29-31 added; cerebral palsy added to investigational policy statement.</td>
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<td>06/14/13</td>
<td>Update Related Policies. Change title for 7.01.69 to “Sacral Nerve Neuromodulation/Stimulation”.</td>
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<td>09/09/13</td>
<td>Clarification note added. This policy does not apply to specialized exercise equipment, such as the RT 300 Exercycle, that is used in the rehabilitation setting under the supervision of a physical therapist or other rehab specialist. Please refer to medical policy 8.03.502.</td>
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<td>12/19/13</td>
<td>Update Related Policies. Remove 1.01.19 as it was archived.</td>
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<td>05/05/14</td>
<td>Annual Review. Policy updated with literature review January 7, 2014. References 20 and 21 added; others renumbered/removed. Policy statement unchanged. All codes removed from policy with the exception of HCPCS codes; these are the only code utilized for adjudication.</td>
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<td>06/27/14</td>
<td>Update Related Policies. Change title to 1.01.17.</td>
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<td>04/24/15</td>
<td>Annual Review. Policy updated with literature review through January 16, 2015; references 20 and 22 added; policy statement retained.</td>
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<td>08/28/15</td>
<td>Update Related Policies. Remove 1.01.17 and 8.01.39 as they were archived.</td>
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<td>11/19/15</td>
<td>Update related policies. Remove 7.01.522.</td>
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<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Literature review. Added reference 36. No change to policy statement. Clarification added on FES devices.</td>
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<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged.</td>
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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.
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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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