

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

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|----------------------------------|--|---|
| <a href="#">POLICY RATIONALE</a> | <a href="#">PRODUCT VARIATIONS DEFINITIONS</a> | <a href="#">DESCRIPTION/BACKGROUND BENEFIT VARIATIONS</a> |
| <a href="#">DISCLAIMER</a>       | <a href="#">CODING INFORMATION</a>             | <a href="#">REFERENCES</a>                                |
| <a href="#">POLICY HISTORY</a>   |  |   |

**I. POLICY**

**Neuromuscular Electrical Stimulation (NMES)**

Neuromuscular electrical stimulation (NMES) to treat muscle atrophy may be considered **medically necessary** when the following criteria are met:

- The nerve supply to the muscle is intact (including brain, spinal cord, and peripheral nerves)
- The patient has any of the following conditions:
  - Previous casting or splinting of a limb
  - Contractures due to scarring from burns
  - Recent hip replacement surgery (until rehabilitation therapy begins)
  - Previous major knee surgery (when there is failure to respond to rehabilitation therapy)

**Functional Neuromuscular Electrical Stimulation**

Functional neuromuscular electrical 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; or
- To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke); or
- To improve ambulation in patients with foot drop caused by congenital disorders (e.g. cerebral palsy) or nerve damage (e.g., post-stroke or in those with multiple sclerosis).

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

*Cross-references:*

- MP-6.020 Transcutaneous Electrical Nerve Stimulation
- MP-6.045 Sympathetic Therapy for the Treatment of Pain
- MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
- MP-6.047 Interferential Current Stimulation
- MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
- MP-6.049 H-Wave Electrical Stimulation
- MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

**II. PRODUCT VARIATIONS**

[TOP](#)

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

**FEP PPO-** Refer to FEP Medical Policy Manual MP-8.03.01, Functional Neuromuscular Electrical Stimulation. The FEP Medical Policy Manual can be found at: [www.fepblue.org](http://www.fepblue.org).

**III. DESCRIPTION/BACKGROUND**

[TOP](#)

Neuromuscular Electrical Stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of NMES:

- **NMES** - used to treat muscle atrophy.
- **Functional Neuromuscular Electrical Stimulation** - used to enhance functional activity of neurologically impaired patients (e.g. spinal cord injury).

**NEUROMUSCULAR ELECTRICAL STIMULATION (NMES)**

Neuromuscular Electrical Stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. NMES is used for the treatment of muscle disuse atrophy. Examples of devices that have 510(k) marketing clearance for the treatment of muscle atrophy include RS Medical’s RS-2m™ 2-channel and RS-4m® 4-channel muscle stimulator.

**FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION**

Functional neuromuscular electrical stimulation (NMES) is an approach to rehabilitation that applies low-level electrical current to stimulate functional movements in muscles affected by

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

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.

**Applications**

***Upper-Extremity Function After Spinal Cord Injury and Stroke***

One application of functional NMES is to restore upper-extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadriplegia). NeuroControl Corp. developed the Freehand System, an implantable upper-extremity neuroprosthesis, to improve the ability to grasp, hold, and release objects for patients with tetraplegia due to C5 or C6 spinal cord injury (SCI). NeuroControl is no longer in business, but NMES centers in the United States and United Kingdom provide maintenance for implanted devices. The NESS H200 (previously known as the Handmaster NMS I system) is an upper-extremity device that uses a forearm splint and surface electrodes. The device, controlled by a user-activated button, is intended to provide hand function (fine finger grasping, larger palmar grasping) for patients with C5 tetraplegia or stroke.

***Footdrop***

Other functional NMES devices have been developed to provide functional NMES for patients with footdrop. Footdrop is weakness of the foot and ankle that causes reduced dorsiflexion and difficulty with ambulation. It can have various causes such as cerebral palsy, stroke, or multiple sclerosis. Functional electrical stimulation of the peroneal nerve has been suggested for these patients as an aid in raising the toes during the swing phase of ambulation. With these devices, a pressure sensor detects heel-off and initial contact during walking. A signal is then sent to the stimulation cuff, initiating or pausing the stimulation of the peroneal nerve, which activates the foot dorsiflexors. Examples of such devices used for treatment of footdrop are the Innovative Neurotronics’ WalkAide, Bioness’s radiofrequency controlled NESS L300, Otto Bock’s MyGait, and the OFDS (Odstock Foot Drop Stimulator). An implantable peroneal nerve stimulator system (ActiGait®) is being developed in Europe.

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

***Ambulation After SCI***

Another application of functional electrical stimulation is to provide patients with SCI the ability to stand and walk. Generally, only SCI patients with lesions from T4 to T12 are considered candidates for ambulation systems. Lesions at T1 to T3 are associated with poor trunk stability, while lumbar lesions imply lower-extremity nerve damage. Using percutaneous stimulation, the device delivers trains of electrical pulses to trigger action potentials at selected nerves at the quadriceps (for knee extension), the common peroneal nerve (for hip flexion), and the paraspinals and gluteals (for trunk stability). Patients use a walker or elbow-support crutches for further support. The electric impulses are controlled by a computer microchip attached to the patient’s belt, which synchronizes and distributes the signals. In addition, there is a finger-controlled switch that permits patient activation of the stepping.

Other devices include a reciprocating gait orthosis with electrical stimulation. The orthosis used is a cumbersome hip-knee-ankle-foot device linked together with a cable at the hip joint. The use of this device may be limited by the difficulties in donning and doffing the device.

***Other Applications***

Other devices, such as the ReGrasp (Rehabtronics), are used for rehabilitation rather than home use. Neuromuscular stimulation is also proposed for motor restoration in hemiplegia and treatment of secondary dysfunction (e.g., muscle atrophy, alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways. These applications are not addressed herein.

**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.

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

To date, the Parastep® Ambulation System (Sigmedics, Northfield, IL) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from 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.”<sup>1</sup> FDA product code: MKD.

**IV. RATIONALE**

[TOP](#)

The most recent literature update was performed through January 8, 2018.

**FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION OF THE UPPER LIMB**

**Spinal Cord Injury**

Much of the early published evidence assessing upper-extremity devices to restore function in patients with spinal cord injuries (SCIs) reported on experience with the Freehand System, an implantable device no longer marketed in the United States.<sup>2-5</sup> The published studies have suggested that the device might give patients the ability to grasp and release objects and independence or greater independence in such activities of daily living (ADLs) as using a fork or the telephone in the study setting. User satisfaction was generally high, and most subjects reported continued use of the device at home, although details of specific activities or frequency of use at home were not provided.

Use of the Handmaster NMS I (NESS L200), another upper-extremity device, was reported in a 2000 series of 10 patients with cervical SCIs.<sup>6</sup> After 2 months of training, performance on a defined set of tasks and one or more tasks chosen by the patient was evaluated. In 6 patients, a stimulated grasp and release with either one or both grasp modes (key and palmar pinch) of the Handmaster was possible. Four patients could perform the set of tasks with but not without the Handmaster. One patient continued using the Handmaster during ADLs at home. In another study (2003) using the Handmaster device, 7 subjects with C5 or C6 SCI practiced using the device daily in an effort to regain the ability to grasp, hold, and release objects.<sup>7</sup> All patients were observed 2 to 3 times during the week for 3 weeks, and they were evaluated on their ability to perform the following tasks: pick up a telephone, eat food with a fork, perform an individually selected ADL task, and perform 2 tasks relating to grasping, holding, and releasing certain items. At the end of the study, all 7 subjects successfully used the device for each required task. Improvements occurred in secondary measures of grip strength, finger linear motion, and Fugl-Meyer Assessment scores (the instrument assesses sensorimotor recovery after stroke).

**Stroke**

Alon et al (2002), reporting on a case series of 29 patients, investigated whether the Handmaster system (NESS L200) could improve select hand function in persons with chronic upper-

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

extremity paresis following stroke.<sup>8</sup> The main outcome measures were 3 ADL tasks: lifting a 2-handled pot, holding a bag while standing with a cane, and another ADL chosen by the patient. Secondary measures included lifting a 600-gram weight, grip strength, electrically induced finger motion, Fugl-Meyer Assessment spherical grasp, and perceived pain scale. At the end of the 3-week study period, the percentage of successful trials compared with baseline were: lifting pot, 93% vs 0%, lifting 600-gram weight, 100% vs 14%; and lifting bag, 93% vs 17%. All subjects performed their selected ADLs successfully and improved their Fugl-Meyer Assessment scores using the neuroprosthesis.

**Section Summary: Functional Neuromuscular Electrical Stimulation of the Upper Limb**

The evidence on functional NMES for the upper limb in patients with SCI or stroke includes a limited number of small case series. Interpretation of the evidence for upper-extremity neuroprostheses for these populations is limited by the small number of patients studied and lack of data demonstrating its utility outside the investigational (study) setting.

**FUNCTIONAL NMES FOR CHRONIC FOOTDROP**

**Stroke**

Functional NMES with a footdrop stimulator (WalkAide) was compared with an ankle-foot orthosis (AFO) in a 2014 industry-sponsored multicenter RCT (NCT01087957) that included 495 Medicare-eligible individuals who were at least 6 months poststroke.<sup>9</sup> A total of 399 individuals completed the 6-month study. Primary outcome measures were the 10-Meter Walk Test (10MWT), a composite measure of daily function, and device-related serious adverse events. Seven secondary outcome measures assessed function and quality of life. The intention-to-treat analysis found that both groups improved walking performance over the 6 months, and the NMES device was found noninferior to the AFO for the primary outcome measures. Only the WalkAide group showed significant improvements from baseline to 6 months on several secondary outcome measures, but there were no statistically significant between-group differences for any outcome.

FASTEST (NCT01138995) was a 2013 industry-sponsored, single-blinded, multicenter trial that randomized 197 stroke patients to 30 weeks of a footdrop stimulator (NESS L300) or a conventional AFO.<sup>10</sup> The AFO group received transcutaneous electrical nerve stimulation at each physical therapy visit during the first 2 weeks to provide a sensory control for stimulation of the peroneal nerve received by the NESS L300 group. Evaluation by physical therapists blinded to group assignment found that both groups improved gait speed and other secondary outcome measures over time, with a similar improvement in the 2 groups. There were no between-group differences in the number of steps per day at home, which was measured by an activity monitor over a week. User satisfaction was higher with the footdrop stimulator.

Secondary analysis of data from this study was reported by O’Dell et al (2014).<sup>11</sup> Comfortable gait speed was assessed in the 99 individuals from the NESS L300 group at 6, 12, 30, 36, and 42 weeks, with and without the use of the footdrop stimulator. A responder was defined as one achieving a minimal clinically important difference of 0.1 m/s on the 10MWT or advancing by at

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

least 1 Perry Ambulation Category (which measures functional walking ability in the home or community). Noncompleters were classified as nonresponders. Seventy percent of participants completed the assessments at 42 weeks, and 67% of participants were classified as responders. Of the 32 participants classified as nonresponders, 2 were nonresponders, and 30 were noncompleters. The percentage of patients in the conventional AFO group classified as responders at 30 weeks was not reported. There were 160 adverse events, of which 92% were classified as mild. Fifty percent of the adverse events were related to reversible skin issues, and 27% were falls.

**Multiple Sclerosis**

An RCT by Barrett et al (2009) assessed functional NMES to improve walking performance in patients with multiple sclerosis.<sup>12</sup> Fifty-three patients with secondary progressive multiple sclerosis and unilateral dropped foot were randomized to an 18-week program of an Odstock Dropped Foot Stimulator device or a home exercise program. Patients in the stimulator group were encouraged to wear the device most of the day, switching it on initially for short walks and increasing daily for 2 weeks, after which they could use the device without restriction. Subjects in the control group were taught a series of exercises tailored to the individual to be done twice daily. Six patients in the NMES group and 3 in the exercise group dropped out, leaving 20 in the NMES group and 24 in the exercise group. The primary outcome measure was walking speed over a 10-meter distance. At 18 weeks, the exercise group walked significantly faster than the NMES group (p=0.028). The authors noted a number of limitations of their study: power calculations were based on the 10-meter walking speed measure only and indicated that 25 subjects would be required in each group, patients were highly selected, clinical assessors also provided treatment (compromising blinding), and the validity and reliability of the 3-minute walk test have not been confirmed (fatigue prevented use of the validated 6-minute test). In addition, subjects in the exercise group were told they would receive a stimulator at the end of the trial, which may have biased exercise adherence and retention in the trial.

A 2010 publication by the same investigators reported on the impact of 18 weeks of physical therapy exercises or ODFS use on ADLs.<sup>13</sup> Results of 53 patients from the trial previously described were reported, using the Canadian Occupational Performance Measure. The Canadian Occupational Performance Measure is a validated semi-structured interview (higher scores indicate improvement) originally designed to assist occupational therapy interventions. The interviews at baseline identified 265 problems of which 260 activities were related to walking and mobility. Subjective evaluation at 18 weeks showed greater improvements in performance and satisfaction scores in the NMES group (35% of the identified problems increased by a score of ≥2) than in the exercise group (17% of problems increased by a score of ≥2). The median satisfaction rating improved from 2.2 to 4.0 in the NMES group and remained stable (2.6 to 2.4) in the exercise group. The median number of falls recorded per patient over the 18-week study was 5 in the NMES group and 18 in the exercise group. About 70% of the falls occurred while not using the NMES device or an AFO.

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

A study by Stein et al (2010) assessed the orthotic and therapeutic effects of NMES in 32 patients with progressive footdrop (31 multiple sclerosis, 1 familial spastic paresis).<sup>14</sup> With the stimulator on (orthotic effect), walking speed improved by 2% for the figure-8 test and by 4% for the 10MWT. With the stimulator off (therapeutic effect), walking speed at 3 months had improved by 9% for the figure-8 test and by 5% for the 10MWT compared with baseline. The combined improvement in walking speed over the 3 months was 13% for the figure 8 (0.61 m/s vs 0.53 m/s) and 13% for the 10MWT (0.88 m/s vs 0.78 m/s), both respectively. The 20 (63%) subjects who returned for testing at 11 months did not show continued improvement compared with 3-month test results, with a combined (orthotic and therapeutic) improvement of 13% on the figure 8 (0.62 m/s vs 0.55 m/s) and 10% on the 10MWT (0.86 m/s vs 0.78 m/s), both respectively, compared with baseline. The Physiological Cost Index did not improve significantly (0.73 beats/min vs 0.78 beats/min, respectively). Subjects with nonprogressive footdrop used the device for an average 85% of days, 9.2 hours per day, and walked about 2 km per day.

**Cerebral Palsy**

Cauraugh et al (2010) conducted a systematic review and meta-analysis of 17 studies on NMES and gait in children with cerebral palsy.<sup>15</sup> Fourteen studies used a pretest-posttest that included a within-subjects design. A total of 238 participants had NMES. Included were studies on acute NMES, functional NMES, and therapeutic NMES (continuous subthreshold stimulation). Five studies examined functional NMES, and one of these studies examined percutaneous NMES. There were 3 outcome measures for impairment: range of motion, torque/movement, and strength/force. There were 6 outcome measures for activity limitations: gross motor functions, gait parameters, hopping on 1 foot, 6-minute walk, Leg Ability Index, and Gillette Gait Index. Moderate effect sizes were found for impairment (0.616) and activity limitations (0.635). Studies selected for the review lacked blinding and were heterogeneous for outcome measures. Reviewers did not report whether any study used a commercially available device.

A 2012 report examined the acceptability and effectiveness of a commercially available footdrop stimulator in 21 children with mild cerebral palsy, gait impairments, and unilateral footdrop.<sup>16</sup> Three children who did not improve walking did not complete the study. Gait analysis in the remaining 18 showed improved dorsiflexion compared with baseline. There was no significant change in other gait parameters, including walking speed. Average daily device use was 5.6 hours (range, 1.5-9.4 hours) over the 3-month study, although participants had been instructed to use the device for at least 6 hours per day. Eighteen (86%) children kept using the device after the 3-month trial. Data from this period were collected but not reported.

Meilahn (2013) assessed the tolerability and efficacy of a commercially available device in 10 children (age, 7-12 years) with hemiparetic cerebral palsy who typically wore an AFO for correction of footdrop.<sup>17</sup> All children tolerated the fitting and wore the device for the first 6 weeks. The mean wear times were 8.4 hours per day for the first 3 weeks and 5.8 hours per day for the next 3 weeks. Seven (70%) children wore the device for the 3-month study period, with average device use of 2.3 hours daily (range, 1.0-6.3 h/d). Six (60%) children continued to use



<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

the neuroprosthesis after study completion. Gait analysis was performed, but quantitative results were not reported. Although half of the subjects improved their gait velocity, the mean velocity was relatively unchanged with the neuroprosthesis.

**Section Summary: Functional NMES for Chronic Footdrop**

For chronic poststroke footdrop, 2 large RCTs comparing NMES with a standard AFO showed improved patient satisfaction with NMES but no significant differences between groups in objective measures like walking. An RCT with 53 subjects examining neuromuscular stimulation for footdrop 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. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be confirmed in a larger number of patients. The literature on NMES in children with cerebral palsy includes a systematic review of small studies with within-subject designs. Two within-subject studies evaluated tolerability and efficacy of a commercially available device in this population. Both studies, which should be considered preliminary investigations, showed no improvement in walking speed with the device. Further study in a larger number of subjects over a longer duration is needed to permit conclusions on the effect of the technology on health outcomes.

**AMBULATION IN PATIENTS WITH SCI**

The clinical impact of the Parastep device rests on the identification of clinically important outcomes. The primary purpose of this device is to provide a degree of ambulation that improves patient ability to complete the ADLs or positively affect the patient’s quality of life. Physiologic outcomes (i.e., conditioning, oxygen uptake) have also been reported, but they are intermediate, short-term outcomes.

The largest study (Chaplin, 1996) reported on ambulation outcomes using the Parastep 1 and included 91 patients.<sup>18</sup> Of these 91 patients, 84 (92%) were able to take steps, and 31 (34%) were able eventually to ambulate without assistance from another person. Duration of use was not reported. Other studies on the Parastep device include a series from the same group of investigators, which focused on different outcomes in the same group of 13 to 16 patients.<sup>19-23</sup> Guest et al (1997) reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury.<sup>22</sup> The group’s mean peak distance walked was 334 meters, but individual studies varied widely. The mean peak duration of walking was 56 minutes, again with wide variability. Anthropomorphic measurements were taken at various anatomic locations. Increases in thigh and calf girth, thigh cross-sectional area, and calculated lean tissue were all statistically significant. The authors emphasized that the device was not intended as an alternative to a wheelchair, and thus other factors such as improved physical and mental well-being should be considered when deciding whether to use the system. The same point was noted in a review article by Graupe and Kohn (1998).<sup>24</sup>

Brissot et al (2000) found that 13 of 15 patients evaluated in a case series achieved independent ambulation.<sup>25</sup> Five of the 13 patients continued using the device for physical fitness at home, but none used it for ambulation. Sykes et al (1996) found low use of a reciprocating gait orthosis

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

device with or without stimulation over an 18-month period,<sup>26</sup> and Davis et al (2001) found mixed usability/preference scale results for ambulation, standing, and transfers with a surgically implanted neuroprosthesis in 12 patients followed for 12 months.<sup>27</sup> The effects of a surgically implanted neuroprosthesis on exercise, standing, transfers, and quality of life were also reported in 2012.<sup>28,29</sup> The device used in both studies was not commercially available at that time.

Several publications reported on physiologic responses to use of the Parastep device. Jacobs et al (1997) found a 25% increase in time to fatigue and a 15% increase in peak oxygen uptake, consistent with an exercise training effect.<sup>20</sup> Needham-Shropshire et al (1997) reported no relation between use of the Parastep device and bone mineral density, although the interval between measurements (12 weeks) and the precision of the testing device might have limited the ability to detect a difference.<sup>21</sup> Nash et al (1997) reported that use of the Parastep device was associated with an increase in arterial inflow volume to the common femoral artery, perhaps related to the overall conditioning response to the Parastep.<sup>23</sup>

**Section Summary: Ambulation in Patients with SCI**

The evidence on functional NMES for standing and walking in patients with SCI consists of case series. Case series are considered adequate for this condition because there is no chance for ambulation in patients with SCI between segments T4 to T12. As stated by various authors, these systems are not designed as alternatives to a wheelchair and offer, at best, limited, short-term ambulation. Some studies have reported improvements in intermediate outcomes, but improvement in health outcomes (e.g., ability to perform ADLs) have not been demonstrated. Finally, evaluations of these devices were performed immediately after initial training or during limited study period durations. There are no data in which patients remained compliant and committed with long-term use.

**SUMMARY OF EVIDENCE**

For individuals who have loss of hand and upper-extremity function due to SCI or stroke who receive functional 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 SCI or stroke includes a few small case series. Interpretation of the evidence is limited by the low 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 the 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 and a systematic review. Relevant outcomes are functional outcomes and quality of life. For chronic poststroke footdrop, 2 large randomized trials 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

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

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 that feature 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 SCI 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 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 (e.g., 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.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

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.<sup>30</sup> 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.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

In 2002 (updated in 2006), Medicare issued a national coverage policy recommending coverage for neuromuscular electrical stimulation (NMES) for ambulation in spinal cord injury patients consistent with the Food and Drug Administration labeling for the Parastep device.<sup>31</sup> 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:

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;

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

3. Persons who demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
4. Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;
5. Persons that can transfer independently and can demonstrate standing tolerance for at least 3 minutes;
6. Persons that can demonstrate hand and finger function to manipulate controls;
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; and
9. Persons that have demonstrated a willingness to use the device long-term.”

The exclusion criteria are as follows:

1. “Persons with cardiac pacemakers;
2. Severe scoliosis or severe osteoporosis;
3. Skin disease or cancer at area of stimulation;
4. Irreversible contracture; or
5. Autonomic dysreflexia.”

**National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12)**

**Treatment of Muscle Atrophy**

“Coverage of NMES to treat muscle atrophy is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins).” See NCD 160.12 for additional information.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

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

**Table 1. Summary of Key Trials**

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

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

POLICY TITLE	NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION
POLICY NUMBER	MP-6.051

**V. DEFINITIONS**

[TOP](#)

**510 (K)** is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

**VI. BENEFIT VARIATIONS**

[TOP](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

**VII. DISCLAIMER**

[TOP](#)

*Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

**VIII. CODING INFORMATION**

[TOP](#)

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

**Investigational; therefore, not covered:**

HCPCS 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

**Covered when medically necessary:**

HCPCS Code	Description
E0745	Neuromuscular stimulator, electronic shock unit

ICD-10-CM Diagnosis Code	Description
M62.50	Muscle wasting and atrophy, not elsewhere classified, unspecified site
M62.511	Muscle wasting and atrophy, not elsewhere classified, right shoulder
M62.512	Muscle wasting and atrophy, not elsewhere classified, left shoulder
M64.519	Muscle wasting and atrophy, not elsewhere classified, unspecified shoulder
M62.521	Muscle wasting and atrophy, not elsewhere classified, right upper arm
M62.522	Muscle wasting and atrophy, not elsewhere classified, left upper arm
M62.529	Muscle wasting and atrophy, not elsewhere classified, unspecified upper arm
M62.531	Muscle wasting and atrophy, not elsewhere classified, right forearm
M62.532	Muscle wasting and atrophy, not elsewhere classified, left forearm
M62.539	Muscle wasting and atrophy, not elsewhere classified, unspecified forearm
M62.541	Muscle wasting and atrophy, not elsewhere classified, right hand
M62.542	Muscle wasting and atrophy, not elsewhere classified, left hand
M62.549	Muscle wasting and atrophy, not elsewhere classified, unspecified hand
M62.551	Muscle wasting and atrophy, not elsewhere classified, right thigh
M62.552	Muscle wasting and atrophy, not elsewhere classified, left thigh
M62.559	Muscle wasting and atrophy, not elsewhere classified, unspecified thigh
M62.561	Muscle wasting and atrophy, not elsewhere classified, right lower leg
M62.562	Muscle wasting and atrophy, not elsewhere classified, left lower leg
M62.569	Muscle wasting and atrophy, not elsewhere classified, unspecified lower leg
M62.571	Muscle wasting and atrophy, not elsewhere classified, right ankle and foot
M62.572	Muscle wasting and atrophy, not elsewhere classified, left ankle and foot
M62.579	Muscle wasting and atrophy, not elsewhere classified, unspecified ankle and foot
M62.58	Muscle wasting and atrophy, not elsewhere classified, other site

<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

ICD-10-CM Diagnosis Code	Description
M62.59	Muscle wasting and atrophy, not elsewhere classified, multiple sites
Z47.1	Aftercare following joint replacement surgery

**IX. REFERENCES**

[TOP](#)

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<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

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<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

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**X. POLICY HISTORY**

[TOP](#)

<b>MP 6.051</b>	<b>CAC 10/25/11</b> New Policy, information regarding NMES and NMES/FES removed from Electrical Stimulation policy and created in this separate policy. Policy
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<b>POLICY TITLE</b>	<b>NEUROMUSCULAR AND FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP-6.051</b>

	statement unchanged, NMES for muscle atrophy remains medically necessary; NMES/FES remains investigational.
	<b>04/09/13-</b> E0770 and E0764 added as Investigational
	<b>CAC 6/4/13</b> Consensus review. Congenital disorder (e.g. cerebral palsy) was added as another example to the statement related to improve ambulation in patients with foot drop for functional neuromuscular electrical stimulation. References updated. FEP variation revised to refer to the FEP policy manual.
	<b>CAC 3/25/14</b> Consensus review. No change to policy statements. References updated. Rationale section added. No coding changes.
	<b>CAC 3/24/15</b> Consensus review. No change to the policy statements. References and rationale updated. Codes reviewed.
	<b>CAC 3/29/16</b> Consensus review. No change to policy statements. References and rationale updated. Coding reviewed.
	<b>Admin update 1/1/17:</b> Product variation section reformatted.
	<b>CAC 5/23/17</b> Consensus. No change to policy statements. References and rationale updated. Coding reviewed.
	<b>1/1/18 Admin Update:</b> Medicare variations removed from Commercial Policies.
	<b>3/20/18</b> Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	<b>10/31/18</b> Coding updated. Added diagnosis codes.

[Top](#)

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