Functional Neuromuscular Electrical Stimulation

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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 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 [MS]).

Background/Overview

NEUROMUSCULAR PROSTHETICS

Neural prosthetic 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 (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.

One application of functional neuromuscular electrical stimulation (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. 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.

Other neural prosthetic 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.

Another application of functional electrical stimulation is to provide patients with spinal cord injury the ability to stand and walk. Generally, only spinal cord injury 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 putting the device on and taking it off.

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In 1997, the Freehand®‡ System was approved by the U.S. 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.

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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 September 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 July 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 by assisting 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 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.

Centers for Medicare and Medicaid Services (CMS)
In 2002, Medicare issued a national coverage policy recommending coverage for NMES for ambulation in spinal cord injury patients consistent with the FDA labeling for the Parastep device, effective April 1, 2003. The Medicare decision memorandum indicates that Medicare considered the same data as those discussed here in their decision-making process. The decision memorandum notes that the available studies are 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 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 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; or
5. Autonomic dysreflexia.

Rationale/Source

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

Functional Neuromuscular Electrical Stimulation of the Upper Limb
Spinal Cord Injury

Most of the early published evidence for upper-extremity devices to restore function in patients with spinal cord injuries (SCIs) report experience with the Freehand System, an implantable device no longer marketed in the United States. The published studies suggest that the device may 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 are not provided.

Use of the Handmaster NMS I (NESS L200), another upper extremity device, was reported in a series of 10 patients with cervical SCIs. After 2 months of training, performance on a defined set of tasks and 1 or more tasks chosen by the patient was evaluated. In 6 patients, a stimulated grasp and release with either 1 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 using the Handmaster device, 7 subjects with C5 or C6 SCI practiced using the device daily with 1 hand to regain the ability to grasp, hold, and release objects. They were observed 2 to 3 times weekly for 3 weeks, and their ability to pick up a telephone, eat food with a fork, and perform an individually selected ADL task plus 2 grasp, hold, and release tasks was evaluated. At the end of the study, all 7 subjects successfully used the device in the studied ADLs and grasp, hold, and release tasks. Improvements occurred in secondary measures of grip strength, finger linear motion, and Fugl-Meyer Assessment (FMA; instrument used to assess sensorimotor recovery after stroke) scores.

Stroke
Alon et al, reporting on a case series of 29 patients, investigated whether the Handmaster system (NESS L200) could improve selected hand function in persons with chronic upper-extremity paresis following stroke. 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, FMA spherical grasp, and perceived pain scale. At the end of the 3-week study period, the percent of successful trials compared with baseline were: lifting pot, 93% versus 0%, lifting 600-gram weight, 100% versus 14%; and lifting bag, 93% versus 17%, all respectively. All subjects performed their selected ADLs successfully and improved their FMA 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. 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 (AEs). There were 7 secondary outcome measures that assessed function and quality of life. Intention-to-treat analysis found that both groups improved walking performance over the 6 months, and the NMES device was 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) is 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. 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 similar improvement in the 2 groups. There were no between-group differences in the number of steps per day at home, which were 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 in 2014. 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 use of the

footdrop stimulator. A responder was defined as achieving a minimal clinically important difference (MCID) of 0.1 m/s on the 10MWT or advancing by at least 1 Perry Ambulation Category. 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 AEs, of which 92% were classified as mild. Fifty percent of the AEs were related to reversible skin issues and 27% were falls.

Multiple Sclerosis
In 2009, an RCT by Barrett et al assessed functional NMES to improve walking performance in patients with MS. Fifty-three patients with secondary progressive MS and unilateral dropped foot were randomized to an 18-week program of an Odstock Dropped Foot Stimulator (ODFS) 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 the impact of 18 weeks of physical therapy exercises or the ODFS on ADLs. Results of 53 patients from the trial previously described were reported, using the Canadian Occupational Performance Measure (COPM). The COPM is a validated semistructured interview (higher scores show improvement) originally designed to assist the design of 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 problems had an increased score of ≥ 2) than in the exercise group (17% of problems had an increased 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.

A study by Stein et al (2010) assessed the orthotic and therapeutic effects of NMES in 32 patients with progressive footdrop (31 MS, 1 familial spastic paresis). With the stimulator on (orthotic effect), walking speed improved by 2% for the figure-8 test and 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 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 when 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 conducted a 2010 systematic review and meta-analysis of 17 studies on NMES and gait in children with cerebral palsy. Fourteen studies used a pretest-posttest, 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 1 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 systematic review lacked blinding and were heterogeneous for outcome measures. The review did not report whether any of the studies used a commercially available device.

A 2012 report examined the acceptability and effectiveness of a commercially available footdrop stimulator in 21 children with mild gait impairments and unilateral footdrop. 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.

In 2013, Meilahn 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. All children tolerated the fitting and wore the device for the first 6 weeks. 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 the neuroprosthesis after study completion. Gait analysis was performed, but quantitative results were not reported. Although half of the subjects improved gait velocity, mean velocity was relatively unchanged with the neuroprosthesis.

Section Summary: Functional NMES for Chronic Footdrop
For chronic poststroke footdrop, 2 large RCTs comparing NMES to 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 MS 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, this 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. 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 identification of clinically important outcomes. The primary purpose of the Parastep 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 (ie, 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 in 91 patients. 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. In 1997, Guest et al reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury. 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 is 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.

Brissot et al (2000) found that 13 of 15 patients evaluated in a case series achieved independent ambulation. Five of the 13 patients continued using the device for physical fitness at home, but none used it for ambulation. Sykes et al found low use of a reciprocating gait orthosis device with or without stimulation over an 18-month period, and Davis et al found mixed usability/preference scale results for ambulation, standing, and transfers with a surgically implanted neuroprosthesis in 12 patients followed for 12 months. The effects of a surgically implanted neuroprosthesis on exercise, standing, transfers, and quality of life were reported in 2012. The device used in both studies is not commercially available at this time.

Several publications reported on physiologic responses to use of the Parastep device. Jacobs et al found a 25% increase in time to fatigue and a 15% increase in peak oxygen uptake, consistent with an exercise training effect. 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 may have limited the ability to detect a difference. 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.

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 (eg, 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 whether 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 spinal cord injury 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 spinal cord injury 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 (eg, 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 obtain 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 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. 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.

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Policy History

Original Effective Date: 05/12/2003
Current Effective Date: 12/20/2017

04/25/2003	Medical Policy Committee review
05/12/2003	Managed Care Advisory Council approval
05/03/2005	Medical Director review
05/17/2005	Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
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
08/15/2007	Medical Policy Committee approval Coverage eligibility unchanged. Rationale /Source updated.
08/06/2009	Medical Policy Committee approval.

Functional Neuromuscular Electrical Stimulation

Policy # 00042
Original Effective Date: 05/12/2003
Current Effective Date: 12/20/2017

08/26/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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
09/23/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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.

Next Scheduled Review Date: 12/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Functional Neuromuscular Electrical Stimulation

Policy # 00042
Original Effective Date: 05/12/2003
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code			
CPT	64565, 95971, 95972			
HCPCS	C1883, E0764, E0770			
ICD-10 Diagnosis	E08.3211-E08.3299	E08.3311-E08.3399	E08.3411-E08.3499	E08.3511-E08.3599
	E08.37X1-E08.37X9	E09.3211-E09.3299	E09.3311-E09.3399	E09.3411-E09.3499
	E09.3511-E09.3519	E09.3521-E35.3599	E09.37X1-E09.37X9	E10.10-E10.29
	E10.311-E10.319	E10.3211-E10.3299	E10.3311-E10.3399	E10.3411-E10.3499
	E10.3511-E10.3599	E10.36-E10.39	E10.37X1-E10.37X9	E10.40-E10.49
	E10.51-E10.59	E10.610-E10.649	E10.65-E10.69	E10.8-E10.9
	E11.00-E11.29	E11.311-E11.39	E11.3211-E11.3299	E11.3311-E11.3399
	E11.40-E11.49	E11.51-E11.59	E11.610-E11.649	E11.65-E11.69
	E11.3411-E11.3499	E11.3511-E11.3599	E11.37X1-E11.37X9	E11.40-E11.49
	E11.51-E11.59	E11.610-E11.649	E11.65-E11.69	E11.8-E11.9
	E13.00-E13.59	E13.3211-E13.3399	E13.3411-E13.3499	E13.3511-E13.3599
	E13.37X1-E13.37X9	E13.610-E13.649	E13.65-E13.69	E13.8-E13.9
	G04.1	G35	G81.00-G81.94	G82.20-G82.54
	G83.10-G83.34	G83.9	O24.011-O24.019	O24.02-O24.03
	O24.111-O24.13	O24.311-O24.319	O24.32-O24.33	O24.811-O24.819
	O24.82-O24.83	O24.911-O24.919	O24.92-O24.93	

*****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. 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, 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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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