8.03.01	Functional Neuromuscular Electrical Stimulation		
Original Policy Date:	April 30, 2015	**Effective Date:**	May 1, 2023
Section:	8.0 Therapy	**Page:**	Page 1 of 31

Policy Statement

I. Neuromuscular stimulation is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes its use in **any** of the following situations:
   A. As a technique to provide ambulation in individuals with spinal cord injury.
   B. To improve ambulation in individuals with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., poststroke, or in those with multiple sclerosis)
   C. To provide upper-extremity function in individuals with nerve damage (e.g., spinal cord injury or poststroke)

II. Functional electrical stimulation devices for exercise in individuals with spinal cord injury is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

There are no specific CPT codes for functional neuromuscular electrical stimulation devices and associated services. The associated training required for the use of a device would probably be coded as physical therapy visits, such as:

- **97530**: Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
- **97760**: Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
- **97763**: Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes

HCPCS code E0764 is specific to a functional neuromuscular stimulator, such as the Parastep, to be used in spinal cord injury patients as an aid in ambulation.

HCPCS code E0770 can be used for other types of functional neuromuscular stimulators such as the stimulators used in individuals with footdrop.

Description

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

Related Policies

- Microprocessor-Controlled Prostheses for the Lower Limb
- Myoelectric Prosthetic and Orthotic Components for the Upper Limb
- Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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

Table 1. Functional Electrical Stimulation Devices Cleared by the FDA

Device	Manufacturer	Device Type	Clearance	Date	Product Code
NESS H200® (previously Handmaster)	Bioness	Hand stimulator	K022776	2001	GZI
MyndMove System	MyndTec	Hand stimulator	K170564	2017	GZI/IPF
ReGrasp	Rehabtronics	Hand stimulator	K153163	2016	GZI/IPF
WalkAide® System	Innovative Neurotronics (formerly NeuroMotion)	Foot drop stimulator	K052329	2005	GZI
ODFS® (Odstock Dropped Foot Stimulator)	Odstock Medical	Foot drop stimulator	K050991	2005	GZI
ODFS® Pace XL	Odstock Medical	Foot drop stimulator	K171396	2018	GZI/IPF
L300 Go	Bioness	Foot drop stimulator	K190285	2019	GZI/IPF
L100 Go	Bioness	Foot drop stimulator	K200262	2020	GZI/IPF
Foot Drop System	SHENZHEN XFT Medical	Foot drop stimulator	K162718	2017	GZI
Nerve And Muscle Stimulator	SHENZHEN XFT Medical	Foot drop stimulator	K193276	2020	GZI
MyGait® Stimulation System	Otto Bock HealthCare	Foot drop stimulator	K141812	2015	GZI
MStim Drop Model LGT-233	Guangzhou Longest Science & Technology	Foot drop stimulator	K202110	2021	GZI/IPF
ERGYS (TTI Rehabilitation Gym)	Therapeutic Alliances	Leg cycle ergometer	K841112	1984	IPF
RT300	Restorative Therapies, Inc (RTI)	Cycle ergometer	K050036	2005	GZI
Myocycle Home	Myolyn	Cycle ergometer	K170132	2017	GZI
Cionic Neural Sleeve NS-100	Cionic	Foot drop stimulator	K221823	2022	GZI/IPF

FDA: U.S. Food and Drug Administration.

To date, the Parastep® Ambulation System (Sigmedics) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the FDA. The Parastep device

is approved to "enable appropriately selected skeletally mature spinal cord injured patients (level C6 to T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury."[1] FDA product code: MKD.

Rationale

Background

Functional Electrical Stimulation

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

Functional electrical stimulation devices consist of an orthotic and a microprocessor-based electronic stimulator with 1 or more channels for delivery of individual pulses through surface or implanted electrodes connected to the neuromuscular system. Microprocessor programs activate the channels sequentially or in unison to stimulate peripheral nerves and trigger muscle contractions to produce functionally useful movements that allow patients to sit, stand, walk, cycle, or grasp. Functional neuromuscular stimulators are closed-loop systems that provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities (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, described in more detail in the Rationale section, include upper-extremity grasping function after spinal cord injury (SCI) and stroke; lifting the front of the foot during ambulation in individuals with foot drop; and ambulation and exercise for patients with SCI. Some devices are used primarily for rehabilitation rather than home use. This evidence review focuses on devices intended for home use.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA

(Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Upper-Extremity Function After Spinal Cord Injury and Stroke

Clinical Context and Therapy Purpose

One application of functional electrical stimulation (FES) 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).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with loss of hand and upper-extremity function due to spinal cord injusry (SCI) or stroke.

Interventions

The therapy being considered is FES. 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 SCI. NeuroControl is no longer in business, but FES 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 hand stimulators that have been cleared for marketing in the United States are:

- ReGrasp by Rehabtronics
- MyndMove by MyndTec. This device is currently being studied in a clinical trial for rehabilitation.

Comparators

The following practices are currently being used to make decisions about FES for upper-extremity paresis: standard of care.

Outcomes

The general outcomes of interest are functional outcomes and quality of life. Specific outcomes of interest include the ability to grasp, hold, and lift objects, along with other selected activities of daily living (ADL).

Available literature indicates training and follow-up for 3 weeks to 2 months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

FreeHand System

Much of the early published evidence assessing upper-extremity devices to restore function in patients with SCIs reported on experience with the Freehand System, an implantable device no longer marketed in the United States.[2,3,4,5,]

Handmaster

Studies with the first version of the NESS H200 (Handmaster), were reported in patients with upper-extremity paresis following stroke and SCI (see Tables 2 and 3).

Alon et al (2003) evaluated the Handmaster device in 7 subjects with C5 or C6 SCI who practiced using the device daily in an effort to regain the ability to grasp, hold, and release objects.[6,] 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).

Alon et al (2002), reporting on a case series of 29 patients, investigated whether the Handmaster system could improve select hand function in persons with chronic upper-extremity paresis following stroke.[7,]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. At the end of the 3-week study period, the percentage 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 subjects performed their selected ADLs successfully and improved their Fugl-Meyer Assessment scores using the neuroprosthesis.

Snoek et al (2000) reported on use of the Handmaster NMS I, another upper-extremity device, for a series of 10 patients with cervical SCIs.[8,] 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.

Table 2. Key Case Series Characteristics

Study	Participants	Treatment	Follow-Up
Alon et al (2003)[6,]	7 patients with C5 or C6 SCI	Handmaster NMS	3 weeks of training
Alon et al (2002)[7,]	29 patients with chronic upper-extremity paresis following stroke	Handmaster NMS	3 weeks of training
Snoek et al (2000)[8,]	10 patients with cervical SCI	Handmaster NMS I	2 months of training

SCI: spinal cord injury

Table 3. Key Case Series Results

Study	Timing	Task 1	Task 2	Task 3
Alon et al (2003)[6,]		Pick up a telephone	Eat with a fork	Individually selected ADL
	Post-training	100%	100%	100%
Alon et al (2002)[7,]		Lifting Pot	Lifting 600-gram weight	Lifting bag
	Baseline	0%	14%	17%
	Post-training	93%	100%	93%
Snoek et al (2000)[8,]		Grasp and Release		

Study	Timing	Task 1	Task 2	Task 3
	Baseline	20%	NA	NA
	Post-training	60%	NA	NA

ADL: activities of daily living; NA: not applicable.

MyndMove

Anderson et al (2022) conducted a multi-center, single-blind, parallel-group, RCT comparing FES delivered by the MyndMove device (n=27) to conventional therapy (n=24) in adults with C4 to C7 SCI.[9,] The FES therapy consisted of 36 to 40 one-hour sessions within a 14-week period, while conventional therapy consisted of the same time frame, but participants received upper limb conventional therapy instead. The primary outcome was the change in baseline of spinal cord injury independence measure III - self-care (SCIM-SC) scores. Both groups gained a mean of 2 points in SCIM-SC scores at the end of treatment, which was clinically meaningful, and this impact persisted at the end of the study (24 weeks from the 1st session). However, there was no statistically significant difference between the groups on any outcomes. This trial was limited by the small number of participants (power was not reached) and interruptions of therapy sessions due to the COVID-19 pandemic lockdown in the U.S. and Canada. Additionally, the participants in the FES group were likely more severely impaired than those in the conventional therapy group based on baseline characteristics. Randomization was stratified by site and not on severity of injury.

Section Summary: Upper-Extremity Function After Spinal Cord Injury and Stroke

The evidence on FES for the upper limbs in patients with SCI or stroke includes a limited number of small case series and an RCT. 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 Electrical Stimulation for Chronic Foot Drop

Clinical Context and Therapy Purpose

Other FES devices have been developed to provide FES for patients with foot drop. Foot drop 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.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with chronic foot drop due to stroke, multiple sclerosis, or cerebral palsy.

Interventions

The therapy being considered is FES.

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 foot drop are:

- WalkAide by Innovative Neurotronics (formerly NeuroMotion)
- L300 Go by Bioness
- MyGait by Otto Bock
- ODFS (Odstock Dropped Foot Stimulator) and ODFS Pace XL by Odstock.

Comparators

The following therapies are currently being used to make decisions about foot drop: standard of care and ankle-foot orthoses (AFO).

Outcomes

The general outcomes of interest are functional outcomes and quality of life. Ability to walk is the primary outcome of interest. There are established measures of walking, mobility and quality of life. These include:

- 10-meter walk test (10MWT): Assesses the time it takes to walk 10 meters
- 6-minute walk test (6MWT): assesses the distance walked in 6 minutes
- Timed Up-and-Go: assesses the time required to get up from a chair and take a step
- Stroke Impact Scale (SIS)

Based on available literature, follow-up would ideally be 6 months to 1 year.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Stroke

Systematic reviews

Two meta-analyses evaluated FES in treatment of patients with foot drop secondary to stroke (Tables 4 through 6).

da Cunha et al (2020) performed a meta-analysis of 14 parallel-group or crossover studies (N =1115) of FES applied to the paretic peroneal nerve.[10,] Compared with supervised exercises alone , FES was not superior in improving gait speed. Functional electrical stimulation significantly improved balance as assessed with the Berg Balance Scale (BBS; ranging from 0 to 56, with higher scores indicating improvement) and functional mobility as assessed by the Timed Up-and-Go test; however, heterogeneity was high for these outcomes. The overall quality of evidence was assessed as low.

Nascimento et al (2020) performed a meta-analysis of 11 parallel-group studies (N =1135) of AFO or FES.[11,] Walking speed was significantly improved compared with no treatment with both AFOs and FES. In comparisons of active treatments, AFO and FES did not significantly differ in outcomes of walking speed or balance as measured by the BBS. However, both analyses included few studies (4 and 2 studies, respectively). The overall quality of evidence was assessed as moderate.

Table 4. Comparison of Studies Included in Meta-Analysis

Study	da Cunha et al (2020)[10,]	Nascimento et al (2020)[11,]
Bae et al (2014)	●	
Bethoux et al (2014)	●	●
Bethoux et al (2015)	●	
Burridge et al (1997)	●	●
Everaert et al (2013)	●	●
Hwang et al (2015)	●	
Kluding et al (2013)	●	●
Kottink et al (2012)	●	
Mitsutake et al (2019)	●	
Morone et al (2012)	●	

Study	da Cunha et al (2020)[10,]	Nascimento et al (2020)[11,]
Park et al (2017)	●	
Salisbury et al (2013)	●	
Sharif et al (2017)	●	
Sheffler et al (2015)	●	●
Daly et al (2011)		●
Erel et al (2011)		●
Nikamp et al (2016)		●
Wilkinson et al (2014)		●
Johnson et al (2004)		●
Embrey et al (2010)		●

Table 5. Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
da Cunha et al (2020)[10,]	1997-2019	14	Post-stroke individuals with foot drop	1115 (16 to 495)	Parallel-group or crossover RCTs	2 to 36 weeks
Nascimento et al (2020)[11,]	1997-2016	11	Post-stroke individuals with foot drop	1135 (20 to 495)	Parallel-group RCTs	6 to 30 weeks

RCT: randomized controlled trial.

Table 6. Meta-Analysis Results

Study	Gait Speed	BBS	Timed Up-and-Go
da Cunha et al (2020)[10,]			
Total N	1077 (12 studies)	780 (5 studies)	780 (5 studies)
Pooled effect (95% CI)	SMD: 0.092 (-0.34 to 0.53)	MD: 2.76 (0.64 to 4.88)	MD: -3.19 (-5.76 to -0.62)
I^2	89%	90%	84%
Nascimento et al (2020)[11,]			
Total N	895 (4 studies)	692 (2 studies)	
Pooled effect (95% CI)	0 (-0.06 to 0.05)	MD: 0.27 (-0.85 to 1.39)	
I^2	56%	0%	

BBS: Berg Balance Scale; CI: confidence interval; MD: mean difference: SMD: standardized mean difference.

Randomized Controlled Trials

Three multicenter RCTs were identified on FES for dropped foot (see Tables 7 and 8).

Hachisuka et al (2021) compared FES with a dropped foot stimulator (WalkAide) with no device treatment in a randomized, open-label trial in 119 patients with post-stroke foot drop who were at least 4 months poststroke.[12,] At 4 weeks, there were no significant differences between groups in the primary endpoint of change from baseline in 6MWT or the secondary endpoint of change from baseline in 10MWT.

Functional electrical stimulation with a dropped foot stimulator (WalkAide) was compared with an AFO in a 2014 industry-sponsored multicenter non-inferiority trial (NCT01087957) that included 495 Medicare-eligible individuals who were at least 6 months poststroke.[13,] A total of 399 individuals completed the 6-month study. Primary outcome measures were the 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 FES 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.

The Functional Ambulation: Standard Treatment versus Electronic Stimulation Therapy (FASTEST) Trial in Chronic Post-Stroke Subjects With Foot Drop (NCT01138995) was a 2013 industry-sponsored, single-blinded, multicenter trial that randomized 197 stroke patients to 30 weeks of a dropped foot stimulator (NESS L300) or a conventional AFO.[14,] 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 foot drop stimulator.

O'Dell et al (2014) reported on a secondary analysis of data from the FASTEST study.[15,] 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 foot drop 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 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.

Table 7. Key RCT Characteristics

Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Hachisuka et al (2021)[12,]	Japan	23	2016-2017	119 patients with post-stroke foot drop	4 weeks with WalkAide	4 weeks with no use of WalkAide
Bethoux et al (2014)[13,]	US	29	2010-2013	495 Medicare-eligible individuals who were at least 6 months poststroke	6 months with WalkAide	6 months with conventional AFO
Kluding et al (2013)[14,] FASTEST	US	11	2010-2013	197 stroke patients	30 weeks of NESS L300	30 weeks with conventional AFO

AFO: ankle-foot orthosis; FASTEST: Functional Ambulation: Standard Treatment vs. Electronic Stimulation Therapy Trial in Chronic Post-Stroke Subjects With Foot Drop; RCT: randomized controlled trial.

Table 8. Key RCT Results

Study	Improvement in 10MWT (m/s)	Daily Function	Improvement in 6MWT (m)	Functional Mobility	Device safety
Hachisuka et al (2021 [12,]	N =119				Serious adverse events
WalkAide	0.06		14.7		0
Control	0.07		22.2		0
p-value	.629		.392		NS
Bethoux et al (2014)[13,]	N =399	Improvement in a composite outcome measure on the SIS		Improvement in Timed Up-and-Go (s)	Serious adverse events
WalkAide	0.186	5.0	33.1	2.2	0
AFO	0.195	3.9	18.0	1.5	2
p-value non-inferiority	<.001	<.001	.17		<.001
Kluding et al (2013)[14,] FASTEST		Change in SIS mobility score			

Study	Improvement in 10MWT (m/s)	Daily Function	Improvement in 6MWT (m)	Functional Mobility	Device safety
L300	0.14±0.16	7.06±13.79	40.9 ± 62.1	−5.93 (13.06)	
AFO	0.15±0.14	5.83±13.26	48.6 ± 51.1	−4.38 (21.37)	
p-value	.75	.52	.34	.54	

6MWT: 6-minute walk test; 10MWT; 10-meter walk test; AFO: ankle-foot orthosis; FASTEST: Functional Ambulation: Standard Treatment vs. Electronic Stimulation Therapy Trial in Chronic Post-Stroke Subjects With Foot Drop; NS: nonsignificant; RCT: randomized controlled trial; SIS: stroke impact scale.

Limitations in study design and conduct are shown in Table 9. The primary limitation for both studies was unequal loss to follow-up, with higher loss to follow-up in the FES group. Inability to tolerate the electrical stimulation has been noted in some studies.

Table 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Hachisuka et al (2021)[12,]		1. Not blinded to treatment assignment				
Bethoux et al (2014)[13,]				1. 19% loss to follow-up with a higher loss to follow-up in the Walk-Aide discontinuing the study		
Kluding et al (2013)[14,]				1. 18% loss to follow-up with a higher loss to follow-up in the L300 group		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Longitudinal Cohort Study

Berenpas et al (2019) compared the effectiveness of implanted FES versus AFO in helping stroke patients with foot drop avoid obstacles while walking ("gait adaptability").[16,]Two cohorts were studied: the first (n=10) was followed for 26 weeks; the second (n=12) was followed for 52 weeks. All study participants had experienced stroke more than 6 months prior and regularly used an AFO. A within-subjects repeated measures design was used. Gait adaptability was tested by having participants walk on a treadmill while obstacles were suddenly dropped in front of the paretic leg. Before implantation of the device, participants were tested using only the AFO (at 2 or 3 km/h). Patients were then implanted with a 4-channel peroneal nerve stimulator (ActiGait). Testing was then conducted with FES and with AFO at 2 weeks postimplantation, then at 8 weeks, 26 weeks, and, for

the second cohort, 52 weeks. Available response time (ART) was calculated "as the time between obstacle release and the moment the toe would have crossed the front edge of the obstacle in the case of an unaltered step." Available response time was stratified into 3 categories based on at what point in the gait cycle the obstacle was dropped: 450 to 600 ms (mid stance), 300 to 450 ms (late stance/early swing), and 150 to 300 ms (mid swing). Results showed FES success rates were an average of 4.7% higher than with AFO (55.4% vs. 50.7%; p=.03). Significant differences were seen between the 3 ARTs (p<.001), with higher success rates with longer ARTs. The individual results ranged widely in differences between devices—at 26 weeks they ranged from −29% to 85%. The small sample size and absence of control group limit the study's generalizability, but larger controlled studies would be difficult given the requirements of the intervention.

Multiple Sclerosis

Randomized Controlled Trials

Several RCTs have evaluated FES in patients with multiple sclerosis and foot drop (see Tables 10 and 11).

Prokopiusova et al (2020) performed a randomized trial that compared FES (combined with postural correction) and neuroproprioceptive facilitation and inhibition physiotherapy for 2 months in patients with multiple sclerosis and foot drop.[17,] Main study outcomes were assessed immediately after and 2 months after program completion and included 2-minute walk test, timed 25-foot walk test, Timed Up-and-Go test, Activities-Specific Balance Confidence Scale (ABC), and BBS. While the group treated with FES experienced significant improvements immediately after program completion in ABC and BBS, none of these outcomes significantly differed between groups at either time point. The study was limited by a lack of blinding of patients and clinicians.

Renfrew et al (2019) compared clinical effectiveness of FES versus AFO in their multicenter randomized trial.[18,]The study took place over 12 months and included 85 treatment-naive patients with multiple sclerosis who had had foot drop for more than 3 months. The patients were randomized to receive either an Odstock Dropped Foot Stimulator (n=42) or AFO (n=43). By 12 months, 32 patients (38%) had dropped out of the study. Outcome measurements were taken at baseline, 3, 6, and 12 months (except the Psychological Impact Score, which was measured only at 12 months). The primary outcome measure was the 5-minute self-selected walk test in which participants walked at their preferred pace around a 9.5-m elliptical course for 5 minutes and total distance was recorded. Other outcomes included the timed 25-foot walk test, Multiple Sclerosis Impact Scale-29 (MSIS-29; higher scores indicate a greater impact on life), and the ABC (higher score indicates more confidence). Results are shown in Table 11. Also measured were orthotic effects and oxygen cost of walking. Clinically significant orthotic and therapeutic effects were deemed an observed increase in walking speed of ≥0.05 m/s. The FES group saw a clinically significant ongoing orthotic effect for both walk tests at 3, 6, and 12 months, but the AFO group did not. For total orthotic effect at 12 months, the AFO results for the 5-minute self-selected walk test were clinically significant, but the FES were not. Although both devices improved walking speed at 12 months, the differences in their effects were not significant.

Two publications from 1 RCT were identified on use of a dropped foot stimulator in patients with multiple sclerosis (see Tables 10 and 11). Barrett et al (2009) assessed FES to improve walking performance in patients with multiple sclerosis.[19,] 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 FES group and 3 in the exercise group dropped out, leaving 20 in the FES group and 24 in the exercise group. The primary outcome measure was the 10MWT. At 18 weeks, the exercise group walked significantly faster than the FES group (p=.028).

A 2010 publication by the same investigators reported on the impact of the treatment on ADL.[20,] 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 FES group (35% of the identified problems increased by a score of 2 or more) than in the exercise group (17% of problems increased by a score of 2 or more). The median satisfaction rating improved from 2.2 to 4.0 in the FES 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 FES group and 18 in the exercise group. About 70% of the falls occurred while not using the FES device or an AFO.

Table 10. Summary of Key RCT Characteristics

Study	Countries	Sites	Participants	Interventions	
				Active	Comparator
Prokopiusova et al (2020)[17,]	Czech Republic	1	44 patients with multiple sclerosis and foot drop	2 months of FES in combination with postural correction	Neuroproprioceptive facilitation and inhibition physiotherapy
Renfrew et al (2019)[18,]	Scotland	7	85 treatment-naive patients with multiple sclerosis and >3 months of foot drop	12 months of FES; measured at baseline, 3, 6, 12 months; gradually increased device wear over first 6 weeks	AFO
Barrett et al (2009)[19,]; Esnouf et al (2010)[20,]	EU	1	53 patients with unilateral dropped foot	18 weeks of FES	Twice daily exercises that were tailored to the patient

AFO: ankle-foot orthosis; EU: European Union; FES: functional electrical stimulation; RCT: randomized controlled trial.

Table 11. Summary of Key RCT Results

Study	Walking Pace, m/s	Daily Function	Walking Distance, m	Functional Mobility	Device Safety
Prokopiusova et al (2020)[17,] (N=44)	25-foot walk test, median	NR	2-min walk test, mean	ABC, mean BBS, mean Timed Up-and-Go, median	NR
FES	-0.1	NR	-3.1	ABC, 6.8 BBS, 1.1 Timed Up-and-Go, -0.8	NR
Physiotherapy	0.4	NR	2.4	ABC, -4.5 BBS, 1.1 Timed Up-and-Go, 0.1	NR
p-value	.32	NR	.57	ABC, 0.18 BBS, 0.98 Timed Up-and-Go, 0.23	NR
Renfrew et al (2019)[18,] (N=85)	25-foot walk test, mean (SD)[a] 5-min self-selected walk test, mean (SD)[a]	MSIS-29 (physical), mean, SD	NR	ABC, mean (SD)	NR

Study	Walking Pace, m/s	Daily Function	Walking Distance, m	Functional Mobility	Device Safety
FES	0.95 (0.30) 0.73 (0.26)	34.2 (17.4)	NR	53.7 (20.3)	NR
AFO	0.71 (0.24) 0.96 (0.31)	33.8 (15.2)	NR	52.2 (23.5)	NR
p-value	.043 .0005	.836	NR	.378	NR
Barrett et al (2009)[19], Esnouf et al (2010)[20], (N=44)	10MWT, mean (SD)	Physiologic Cost Index	3-min walk test, mean (SD)	Canadian Occupational Performance Measure	Falls
FES	0.74 (0.026)	0.69 (0.041)	124 (8.5)	35%	5
Exercise	0.82 (0.024)	0.70 (0.037)	112 (7.9)	17%	18
p-value	.028	.81	.334	<.05	.036

10MWT; 10-meter walk test; ABC: Activities-Specific Balance Confidence Scale; AFO: ankle-foot orthosis; BBS: Berg Balance Scale; FES: functional electrical stimulation; MSIS-29 (physical): Multiple Sclerosis Impact Scale physical subscale; m/s: meters per second; NR: not reported; SD: standard deviation; RCT: randomized controlled trial.
[a] At 12 months without use of FES/AFO.

Limitations in relevance and design and conduct are denoted in Tables 12 and 13. In Barrett et al (2009), power calculations were based on the 10MWT 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 had not been confirmed (fatigue prevented use of the validated 6MWT). 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.

Table 12. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Prokopiusova et al (2020)[17], Renfrew et al (2019)[18],		4. Not the intervention of interest			
Barrett et al (2009)[19], Esnouf et al (2010) [20],	3. Patients were highly selected				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 13. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Prokopiusova et al (2020)[17],		1. Patients and clinicians were not blinded				
Renfrew et al (2019)[18],		1,2,3. No blinding employed				3. Confidence intervals not reported
Barrett et al (2009)[19], Esnouf et al (2010)[20],		2,3. Blinding was assessed by the treating physician		6. Not intention-to-treat analysis	2. Loss to follow-up resulted in insufficient power	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Cerebral Palsy

Systematic reviews

Three systematic reviews were identified on the use of a dropped foot stimulator for children with cerebral palsy. Table 14 compares the trials included in each review and Table 15 describes the characteristics of each review.

Cauraugh et al (2010) conducted a systematic review and meta-analysis of 17 studies on FES and gait in children with cerebral palsy.[21] Fourteen studies used a pretest-posttest that included a within-subjects design. A total of 238 participants had FES. Included were studies on acute FES, FES, and therapeutic FES (continuous subthreshold stimulation). Five studies examined FES, one of which examined percutaneous FES. Impairment was assessed by 3 outcome measures: range of motion, torque/movement, and strength/force. Activity limitations were assessed by 6 outcome measures: gross motor functions, gait parameters, hopping on 1 foot, 6MWT, 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.

Zhu et al (2022) conducted a systematic review and meta-analysis of 9 RCTs (N=282) on FES and gait in children with cerebral palsy, including more recent studies than other systematic reviews.[22] Of the children included across studies, 142 were in the FES therapy group and 140 were in the control group, which included comfort treatment, general nursing, or other physical therapy. All studies were included in analysis of walking speed and step length, with no significant heterogeneity among studies. Meta-analysis demonstrated that walking speed was increased after FES compared with the control group (standard mean difference [SMD], 0.82; 95% confidence interval [CI], 0.57 to 1.07; p<.0001). Additionally, FES increased the walking step length compared to the control group (SMD, 1.34; 95% CI, 1.07 to 1.60; p<.0001). Most studies had limitations in blinding methods of participants,

and most of them were single-blind studies. Additionally, there is an overall lack of high-quality RCTs contributing to evidence, and authors concluded that more research with larger populations was needed.

Chen et al (2023) also conducted a systematic review of 14 RCTs measuring the impact of FES on mobility in children with cerebral palsy.[23,] Included RCTs compared FES with placebo or conventional therapy (N=421). While there was overlap of studies included in Cauraugh et al (2010), Chen et al (2023) also included unique studies. Compared with the control group, children who received FES demonstrated greater improvement in walking speed (7 studies, n=213; SMD, 0.29; 95% CI, 0.02 to 0.57; p=.04) and the standing, walking, running, and jumping dimension of the Gross Motor Function Measure (9 studies, n=302; SMD, 1.24; 95% CI, 0.64 to 1.83; p<.0001). Five RCTs (n=198) reported on adverse effects of FES, and no adverse events were reported in any trial. Participants were not blinded in any of the studies and therapists were not blinded in most of the studies. Long-term effects of FES could not be determined based on the short duration of follow-up of included studies. Additionally, parameters and location of the stimulation differed across studies. Despite risk of bias identified across trials, the studies included in this systematic review were deemed to be of moderate quality using the Grading of Recommendations, Assessment, Development and Evaluation method.

Table 14. Comparison of Studies Included in Systematic Reviews and Meta-Analyses

Study	Cauraugh (2010)[21,]	Zhu (2022)[22,]	Chen (2023)[23,]
Hazlewood et al (1994)	●		
Comeaux et al (1997)	●		
Steinbok et al (1997)	●		
Sommerfelt et al (2001)	●		
Dali et al (2002)	●		
van der Linden et al (2003)	●		●
Chan et al (2004)			●
Durham et al (2004)	●		
Johnston et al (2004)	●		
Maenpaa et al (2004)	●		
Ho et al (2006)	●		●
Kerr et al (2006)	●	●	●
Jeronimo et al (2007)	●		
Stackhouse et al (2007)	●		
Xu et al (2007)			●
Jiang et al (2008)			●
Katz et al (2008)	●		
Khalili et al (2008)	●		
Nunes et al (2008)	●		
van der Linden et al (2008)	●	●	●
Yang et al (2008)			●
Al-Abdulwahab et al (2009)			●
Zhang et al (2009)			●
Gao et al (2010)			●
Li et al (2013)			●
Pool et al (2015)		●	
El-Shamy et al (2016)		●	●
Karabay et al (2016)		●	
Pool et al (2016)		●	
Duymuz et al (2018)			●
Armstrong et al (2020)		●	
Özen et al (2021)		●	
Moll et al (2022)		●	

Table 15. Systematic Review and Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Cauraugh (2010)[21,]	1994-2008	17	Children with cerebral palsy receiving FES or other NMES	238 (7 to 82)	RCTs, quasi-experiment (non-randomized), or case-controlled studies	NR
Zhu (2022)[22,]	2006-2022	9	Children with cerebral palsy under 18 years, included in trials comparing FES to a control group that was not another electrical stimulation group	282 (14 to 50)	RCTs	NR
Chen (2023)[23,]	2003-2018	14	Children with spastic cerebral palsy in trials comparing NMES to placebo or conventional therapy	421 (12 to 78)	RCTs (2 crossover studies, 12 parallel group studies)	Range, once to 16 weeks (60 mins, 5 times weekly)

FES: functional electrical stimulation; NMES: neuromuscular electrical stimulation; NR: not reported; RCT: randomized controlled trial.

Section Summary: Functional Electrical Stimulation for Chronic Foot Drop

For chronic poststroke foot drop, a meta-analysis and 2 RCTs comparing FES with a standard AFO showed no significant differences between groups in objective measures such as walking, but the RCTs indicated some improved patient satisfaction with FES. A longitudinal cohort study assessed patients' ability to avoid obstacles while walking on a treadmill using FES versus AFO. Although the FES group averaged a 4.7% higher rate of avoidance, the individual results between devices ranged widely. One RCT with 53 subjects examining neuromuscular stimulation for foot drop in patients with multiple sclerosis showed a reduction in falls and improved patient satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. Another RCT showed that at 12 months, both FES and AFO had improved walking speed, but the difference in improvement between the 2 devices was not significant. 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 FES in children with cerebral palsy includes 3 systematic reviews of small studies with within-subject designs. All included studies only measure short-term results; it is unclear what the long-term effects of FES may be in this population. Further study in a larger number of subjects for a longer duration of study is needed.

Ambulation in Patients With Spinal Cord Injury

Clinical Context and Therapy Purpose

Another application of FES is to provide patients with SCI the ability to stand and walk. 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.

The purpose of FES for ambulation in patients who have SCI is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with SCI at segments T4 to T12.

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.

Interventions
The therapy being considered is FES.

To date, the Parastep Ambulation System (Sigmedics) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the U.S. Food and Drug Administration (FDA). The Parastep device is approved to "enable appropriately selected skeletally mature spinal cord injured patients (level C6 to T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury."[1,]

Comparators
The following therapies are currently being used to make decisions about FES for ambulation: standard of care.

Outcomes
The general outcomes of interest are functional outcomes and quality of life. 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.

Based on available literature, longer-term outcomes would require follow-up of at least 18 months.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
The evidence on FES for ambulation is shown in Table 16.

Chaplin (1996) reported on the largest study, which was on ambulation outcomes using the Parastep 1 and included 91 patients.[24,] 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.[25,26,27,28,29,]

Guest et al (1997) reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury.[28,] 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. Graupe and Kohn (1998) noted the same point in a review article.[30,]

Brissot et al (2000) found that 13 of 15 patients evaluated in a case series achieved independent ambulation.[31,] 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 device with or without stimulation over an 18-month period,[32,] 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.[33,] The effects of a surgically implanted neuroprosthesis on exercise, standing, transfers, and quality of life were also reported in 2012.[34,35,] 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.[26,] 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.[27,] 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.[29,]

Table 16. Key Case Series

Study	Participants	Ambulation, n (%)	Distance walked	Physical Fitness	Limitations
Chaplin et al (1996)[24,]	91 adults with SCI	31 (34%) could ambulate without assistance			84 (92%) could take some steps
Guest et al (1997)[28,]	16 adults with SCI		334 meters	Improvements in the leg	
Brissot et al (2000)[31,]	15 adults with SCI	13 (87%) patients achieved independent ambulation		5 used the device for physical fitness	No patient used the device for ambulation at home

SCI: spinal cord injury.

Section Summary: Ambulation in Patients With Spinal Cord Injury

The evidence on functional FES 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.

Functional Electrical Stimulation Exercise Equipment for Spinal Cord Injuries

Clinical Context and Therapy Purpose

The U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion recommends 2 days per week of muscle strengthening for both healthy adults and adults with disabilities, and at least 150 minutes to 300 minutes (5 hours) of moderate-intensity aerobic activity per week or 75 minutes to 150 minutes of vigorous aerobic activity.[36,] In patients with SCI, inactivity due to injury or barriers to exercise can lead to multiple degenerative changes that include muscle atrophy, bone mass loss and osteoporosis, and reduction in cardiopulmonary function. Other adverse effects of inactivity that are common with SCI include muscle spasms and weight gain, which may predispose individuals to metabolic syndrome, type 2 diabetes, and their associated health problems.

Functional electrical stimulation cycle ergometers are available in rehabilitation facilities. An ergometer is a device that measures work performed by exercising. When the term "ergometer" is used in the context of FES, it refers to exercise equipment that measures both position and speed and stimulates muscles in a prescribed sequence to provide coordinated movement (e.g., cycling) of the paralyzed limb. The devices can provide increasing resistance as work capacity increases, and reduce stimulation when fatigue is detected (e.g., a speed of cycling below 35 rpm). Some models of FES cycle ergometers have been designed for home exercise in individuals with SCI and are the focus of this evidence review.

The proposed benefit of FES exercise equipment is to counteract the health consequences of paralyzed limbs and include:

- Prevention of muscle atrophy
- Reduction of muscle spasms
- Improvement of circulation
- Improvement in range of motion
- Improvement in cardiopulmonary function
- Reduction in pressure sore frequency
- Improvements in bowel and bladder function
- Decreased incidence of urinary tract infections

Hunt et al (2012) conducted a systematic review of the efficiency of FES cycling.[37,] They recommended that future work address factors that limited cycling performance including the crude recruitment of muscle groups, non-optimal timing of muscle activation, lack of synergistic and antagonistic joint control, and non-physiologic recruitment of muscle fibers. The purpose of FES exercise equipment for patients who have SCI and lower extremity paresis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Three specific issues will be addressed in this evidence review:

1. Are there demonstrated health benefits of FES cycle ergometers in patients with SCI?
2. Do the different devices provide similar health benefits?
3. What levels of compliance are needed to obtain a health benefit?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is patients with SCI.

Interventions

The therapy being considered is FES exercise equipment.

The majority of home FES devices are cycle ergometers for the lower limbs of patients with lower extremity paresis, although some devices may also include upper arm exercise. All of the devices have evolved over the past 3 decades. Some have internet capability and can be programmed remotely.

- The REGYS and ERGYS series ergometers are manufactured by Therapeutic Alliances. These devices are the largest, include a computer console, and require transfer to an integrated seat. The ERGYS3 is a fourth generation device; earlier models continue to be utilized.
- There are several models of the RT300 by Restorative Therapies, Inc (RTI). The RT300-S includes both leg and arm cycles. This device is used with the patient's own wheelchair and does not require a transfer.
- The Myocycle Home by Myolyn is designed for home use and is the simplest of the cycle ergometers.
- The StimMaster Orion was manufactured by Electrologic. Electrologic ceased business operations in 2005.

Comparators

The following therapy is currently being used to make decisions about cycle ergometers: standard of care without home exercise equipment.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, and quality of life. Specific outcomes of interest include reduction in muscle atrophy and muscle spasms, reversal of bone mass loss, improvement in circulation and cardiopulmonary function, and quality of life. These should be measured after at least 3 months of exercise in a home environment with self-directed activity, although supervised training protocols may provide useful information regarding the potential health benefits of cycle ergometers.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Four within-subject comparisons of health benefits of the RT300 are described in Table 17. Ralson et al (2013) reported on the short-term effects (2 weeks) of the cycle ergometer and found no significant benefit on urine output, lower limb swelling, and spasticity compared with standard rehabilitation.[38,] Dolbow et al (2013) reported an improvement in quality of life on 2 of 4 domains.[39,] However, only 11 of the original 17 participants who remained in the study after the first 8 weeks were included in this report, and this detail was not reported in the second publication.[40,39,] It is notable that the incentive to remain in the study in the first 8 weeks was strong because the Veterans Affairs Medical Center purchased the devices for participants who met exercise requirements over the first 8 weeks of device rental. In the third study, Johnston et al (2009) conducted an RCT to evaluate the health benefits of home FES cycling in children with a pediatric RT300.[41,] The 3 groups in this study were FES cycling, passive cycling, and electrical stimulation controls. There was no significant difference in health measures across the groups, although the FES group had a greater within-subject improvement in 1 of 4 health measures. Compliance was supervised by parents, who filled out activity logs and had regular contact with study personnel. Because this study was conducted over a decade ago, it is uncertain if newer models of the RT300 would show greater health benefits. Dolbow et al (2021)

evaluated the efficacy of FES cycling (RT300) along with nutrition counseling for 8 weeks in 10 obese adults with SCI.[42,] The participants were treated with either FES cycling plus nutrition counseling (n=5) or nutrition counseling alone (n=5). The cycling group completed high intensity interval cycling for 30 minutes 3 times weekly. The cycling group improved body fat and lean leg mass to a greater extent than those who received nutrition counseling alone.

Table 17. Summary of Studies on the RT300

Study	Study Type	Participants	Treatment	Assessment	Training Duration	Outcome	Limitations
Dolbow et al (2021)[42,]	Prospective comparison	10 individuals with SCI	FES cycling with nutrition counseling or nutrition counseling alone	Body composition, blood glucose levels	8 weeks	Addition of cycling improved body fat percentage and lean leg mass greater than nutrition counseling alone; neither group had a significant change in mean blood glucose	Small sample size and limited duration
Ralston et al (2013)[38,]	Prospective within-subject comparison	14 individuals with recent SCI	2-week crossover of FES cycling 4 times per week with the RT300 or standard rehab	Urine output, lower limb swelling, spasticity	2 weeks	No benefit compared to standard rehab	Only 2 weeks of FES may not have been sufficient
Dolbow et al (2013)[39,]	Prospective within-subject comparison	11 male veterans with SCI (73% with tetraplegia)	Home FES that increased in speed, resistance, and duration over 8 weeks	Quality of Life	8 weeks	Improvement in physical and environmental domains but not psychological and social	Selective reporting of the 11 participants who completed the initial study (Dolbow et al 2012 [40,])
Johnston et al (2009)[41,]	RCT with within-subject comparison	30 children with SCI	Home FES cycling group, with passive cycling and electrical stimulation–only controls	Oxygen uptake, resting heart rate, forced vital capacity, lipid profile	3 times per week for 6 months	There was no significant difference across groups. The FES group showed a greater percent increase in 1 of 4 measures compared with the control groups	Early model of device that may not be representative of current devices

FES: functional electrical stimulation; RCT: randomized controlled trial; SCI: spinal cord injury.

Sadowsky et al (2013) evaluated motor and sensory recovery with long-term use of the ERGYS2.[43,] Individuals with SCI who were treated with FES had positive outcomes on motor and sensory scores compared with individuals who did not receive FES, but the retrospective study was limited by potential for selection bias. The within-subject comparisons in Table 18 uniformly show an improvement in aerobic capacity and metabolism with training. Griffin et al (2009) showed in their prospective study that cycling for 30 minutes, 2 to 3 times per week, for 10 weeks on the ERGYS2 resulted in improvements in a number of physiological measures of health (lean muscle mass, work capacity, glucose tolerance, insulin levels, inflammatory markers) along with an improvement in motor and sensory function.[44,] These positive results are notable for the relatively short training period. A reduction in bone mass and osteoporosis is common in individuals with SCI, but no studies have demonstrated an improvement in bone mineral density. Farkas et al (2021) compared FES leg cycling (ERGYS2) with arm cycling in 13 patients with SCI.[45,] Patients exercised 5 times weekly for 16

weeks with greater improvement in exercise energy expenditure and cardiorespiratory fitness in patients exercising with arm cycling than in patients exercising with FES leg cycling. A major limitation in relevance of the studies for the present evidence review is that they do not appear to have been conducted in the home environment. The REGYS and ERGYS cycle ergometers have a bulky integrated seat and require transfer from a wheelchair, which may be a significant limitation to home use. Sustained motivation to exercise for 2 to 3 times per week outside of the investigational setting is uncertain. (See Table 18 for more study details.)

Table 18. Summary of Studies on the ERGYS2

Study	Study Type	Participants	Treatment	Assessment	Training Duration	Outcome	Limitations
Farkas et al (2021)[45,]	Randomized controlled trial	13 adults with SCI	Arm cycling vs. ERGYS2 cycling	Energy expenditure, cardiometabolic profile, and body composition	16 weeks	Arm cycling improved both energy expenditure and cardiometabolic profile compared with FES; FES improved body fat mass compared with baseline	Small sample size; limited duration
Sadowsky et al (2013)[43,]	Retrospective matched comparison	25 adults with chronic SCI who received FES cycling and 20 individuals with SCI who did not receive FES	Long-term rehabilitation on the ERGYS2	>1-point improvement on the combined motor–sensory scores on the ASIA impairment scale	29 months (range, 3 to 168)	FES improved both motor and sensory scores compared with controls	Potential bias in who was referred for FES
Griffin et al (2009)[44,]	Prospective within-subject comparison	18 adults with SCI	Cycling for 30 min, 2 to 3 times per week on the ERGYS2	ASIA score, body composition, motor and sensory function, and metabolism	10 weeks	Improvement in lean muscle mass, cycling power, work capacity, endurance, glucose tolerance, insulin levels, inflammatory markers, and motor and sensory neurological function	10-week duration of study

ASIA: American Spinal Injury Association (neurological classification of SCI test battery); FES: functional electrical stimulation; SCI: spinal cord injury.

Kressler et al (2014) conducted an analysis of data usage patterns and energy expenditure of 314 individuals over 20,183 home activity sessions with Restorative Therapies FES cycle ergometers (e.g., RT300; see Tables 19 and 20).[46,] With use categorized into low (<2 days/week), medium (2 to 5 days/ week) and high use (at least 5 days/week), 71% of individuals with SCI were considered low users with an average of 0.9 days and 34 minutes of cycling per week. Seven of the 314 individuals were high users (2%) and 83 were medium users (27%). Kressler et al (2014) noted that none of the users met the recommended 1000 kcals/week, with maximal weekly expenditure of 43 kcals.

Table 19. Characteristics of Studies on Home Use of Restorative Therapies Cycle Ergometers

Study	Country	Participants	Treatment Delivery	Follow-Up
Kressler et al (2014)[46,]	US	314 individuals with SCI who had home network-connected Restorative Therapies FES cycle ergometers	Analysis of data on usage patterns and energy expenditure from 314 individuals across 20,183 activity sessions	NR

FES: functional electrical stimulation; NR: not reported; SCI: spinal cord injury.

Table 20. Results on Home Use of Restorative Therapies Cycle Ergometers

Study	Treatment	N (%)	Average days/week (SD)	Average min/week (SD)
Kressler et al (2014)[46,]	<2 days per week	218 (71%)	0.9 (0.4)	34 (21)
	2 to 5 days per week	83 (27%)	3.1 (0.7)	118 (50)
	>5 days per week	7 (2%)	6.3 (1.0)	672 (621)

SD: standard deviation.

Dolbow et al (2012) assessed factors affecting compliance with recommended levels of activity on a home cycle ergometer.[40,] Seventeen veterans with SCI were provided a rental RT300 and instructed to cycle continuously for 40 to 60 minutes, 3 times per week. If the participants achieved the recommended level of exercise, the Veterans Affairs Medical Center would purchase the device. Thus, there was a strong incentive to achieve the recommended level of exercise. Participants were monitored for another 8 weeks after purchase to determine if compliance remained high without the incentive, although participation in a study was also known to improve adherence. Adherence rates were 71.7% for the first 8 weeks and 62.9% for the second 8-week period (not statistically different). The odds of adhering to the exercise program in the first 8 weeks were higher in younger participants (odds ratio [OR], 4.86; p=.02), in participants who were active prior to the study (OR, 4.59; p=.02) and in participants with non-FES pain (OR, 2.22; p=.01). Level of injury, time since injury, and history of depression were not significant factors in adherence. Five older participants dropped out of the study before the second 8-week period began. The remaining participants were included in a subsequent report of the effect of the exercise on quality of life over the 8 weeks of the study.[39,]

Section Summary: Functional Electrical Stimulation Exercise Equipment for Spinal Cord Injuries

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

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

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

National Institute for Health and Care Excellence

In 2009, NICE published guidance stating that the evidence on functional electrical stimulation for foot drop of neurologic origin appeared adequate to support its use.[47,] 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 [ADL]) and these outcomes should be examined in different ethnic and socioeconomic groups.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare (2002; updated in 2006) issued a national coverage policy recommending coverage for neuromuscular electrical stimulation for ambulation in spinal cord injury patients consistent with the U.S. Food and Drug Administration (FDA) labeling for the Parastep device.[1,48,] The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in its decision-making process. The decision memorandum noted that the available studies were flawed but concluded that the limited ambulation provided by the Parastep device supported its clinical effectiveness and thus its coverage eligibility. The inclusion criteria outlined by Medicare are as follows:

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

The exclusion criteria are as follows:

- "Persons with cardiac pacemakers;
- Severe scoliosis or severe osteoporosis;
- Skin disease or cancer at area of stimulation;
- Irreversible contracture; or
- Autonomic dysreflexia."

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 21.

Table 21. Summary of Key Trials

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

NCT: national clinical trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
	97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
	97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
HCPCS	E0744	Neuromuscular stimulator for scoliosis
	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

Type	Code	Description
	E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/03/2009	New Policy Adoption Developed new policy: NMES for disuse atrophy Revised: Electrical/Electromagnetic Stimulation for the Treatment of Arthritis Adopted BCBSA: • Threshold Electrical Stimulation as a Treatment of Motor Disorders • Stimulation of the Sacral Anterior Root Combined with posterior • Sacral Rhizotomy in Patients with Spinal Cord Injury • Functional Neuromuscular Stimulation to Provide Ambulation
11/04/2009	Coding Update
02/08/2010	Coding Update
10/29/2010	Coding Update
07/08/2013	Policy revision with position change
01/30/2015	Coding update
04/30/2015	Policy title change from Neuromuscular, Functional, and Threshold Electrical Stimulation Policy revision without position change
10/01/2016	Policy revision without position change
10/01/2017	Policy revision without position change
01/01/2018	Coding update
05/01/2018	Policy revision without position change
07/01/2019	Policy revision without position change
07/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2021	Annual review. No change to policy statement. Literature review updated.
06/01/2022	Annual review. No change to policy statement. Literature review updated.
05/01/2023	Annual review. Policy statement, guidelines and literature updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with

generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	AFTER Blue font: Verbiage Changes/Additions
Functional Neuromuscular Electrical Stimulation 8.03.01 **Policy Statement:** Neuromuscular stimulation is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes its use in **any** of the following situations: I. As a technique to provide ambulation in patients with spinal cord injury II. To improve ambulation in patients with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., poststroke, or in those with multiple sclerosis) III. To provide upper-extremity function in patients with nerve damage (e.g., spinal cord injury or poststroke) Functional electrical stimulation devices for exercise in patients with spinal cord injury is considered **investigational**.	**Functional Neuromuscular Electrical Stimulation 8.03.01** **Policy Statement:** I. Neuromuscular stimulation is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes its use in **any** of the following situations: A. As a technique to provide ambulation in individuals with spinal cord injury. B. To improve ambulation in individuals with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., poststroke, or in those with multiple sclerosis) C. To provide upper-extremity function in individuals with nerve damage (e.g., spinal cord injury or poststroke) II. Functional electrical stimulation devices for exercise in individuals with spinal cord injury is considered **investigational**.