Anthem

Medical Policy

Subject: Functional Electrical Stimulation (FES); Threshold Electrical Stimulation (TES)
Document #: DME.00022
Status: Revised
Publish Date: 04/10/2024
Last Review Date: 02/15/2024

Description/Scope

This document addresses uses of functional electrical stimulation (FES) and threshold electrical stimulation (TES) devices. FES is used in neurologically impaired individuals, including those with spinal cord injury and stroke, to stimulate muscles during activity. TES, also referred to as therapeutic electrical stimulation, involves the delivery of low intensity electrical stimulation (typically at night) and has been proposed as a treatment of cerebral palsy and scoliosis.

Note: For information regarding devices that may be utilized by individuals with neurological disorders affecting the ability to ambulate without assistance, please see the following document:

- OR-PR.00006 Powered Robotic Lower Body Exoskeleton Devices

Note: FES has been used to treat or prevent muscle disuse atrophy in individuals with neurologic impairment. However, the use of electrical stimulation for the same indication *in individuals without neurologic injury* is addressed in the following document:

- CG-DME-03 Neuromuscular Stimulation in the Treatment of Muscle Atrophy

Position Statement

Investigational and Not Medically Necessary:

Functional electrical stimulation (FES) is considered **investigational and not medically necessary** for all indications, including but not limited to:

A. When used to prevent or reverse muscular atrophy (wasting) and bone demineralization (loss), by stimulating paralyzed limbs for the performance of stationary exercise, or to correct gait disorders. This includes, but is not limited to, functional electrical stimulation ergometer devices (for example, ERGYS® and ERGYS® 2); **or**
B. When used to promote ambulation (for example, Parastep® I System); **or**
C. When used to activate muscles of the upper limb or lower limb to produce functional movement patterns. This includes, but is not limited to, the NESS H200® Handmaster Rehabilitation System, NESS L300™ Foot Drop System, ODFS Dropped Foot Stimulator, and the WalkAide® System.

Threshold electrical stimulation (TES) is considered **investigational and not medically necessary** for all indications including, but not limited to, treatment of motor disorders such as cerebral palsy or scoliosis.

Rationale

Functional Electrical Stimulation

FES is designed to stimulate muscles and thus improve the function of the extremities. FES has primarily been investigated in individuals with neurologic impairment, most prominently following spinal cord injury (SCI), stroke or multiple sclerosis. The stimulation is directed at improving function by utilizing devices intended to restore ambulation in the lower extremity or dexterity and function in the upper extremity; or devices to indirectly improve function, such as exercise devices adapted to FES, which are designed to prevent or treat muscle disuse atrophy. The majority of these devices use surface electrodes, but intramuscular (IM) electrodes have also been used. Standard therapy in individuals with neurologic impairment includes active and passive physiotherapy and the use of various braces and orthoses. Therefore, studies were reviewed that investigate the outcomes of FES compared to these standard therapies.

FES Devices to Prevent Muscle Atrophy and Bone Demineralization

FES has been incorporated into exercycles to treat the lower extremities. For example, the legs are wrapped in fabric strips that contain electrodes to stimulate the muscles, thus permitting the individual to pedal. The resulting exercise is designed to prevent muscular atrophy and bone demineralization. The key outcome in the evaluation of these devices is whether the use of electrical stimulation, permitting active exercise, provides clinically significant incremental improvements, compared to passive devices used for the same purpose. FES cycling (FESC) with devices, such as the ERGYS (K841112) (Therapeutic Alliances Inc., Fairborn, Ohio) and RT300-S/RT300-SP (K050036) (Restorative Therapies, Inc., Baltimore, MD) have received U.S. Food and Drug Administration (FDA) 510(k) clearance as in-home physical therapy and exercise equipment. These devices are indicated for general rehabilitation for: 1) relaxation of muscle spasms; 2) prevention or retardation of disuse atrophy; 3) increasing local blood circulation; and, 4) maintaining or increasing range of motion.

Several randomized controlled trials (RCTs) have evaluated FESC in post-stroke individuals. Janssen and colleagues (2008) randomized 12 post-stroke individuals to receive cycling exercise with and without FES. Outcome measures included aerobic capacity, functional performance and lower limb strength. There were no significant differences in outcomes reported between the two groups. Ambrosini and colleagues (2011) evaluated FES cycling (FESC) (MOTOmed®, RECK GmbH, Betzenweiler, Germany) compared to passive cycling (n=35) to improve lower extremity motor functions and accelerate the recovery in post-hemiparetic individuals. Limitations of these studies included small sample size, short-term follow-up, and conflicting results. Other studies of FESC consist of small case series where the exercycle is used for a limited time as part of a rehabilitation program.

RCTs have also evaluated FESC in individuals with SCI. Johnston and colleagues (2011) evaluated the effect of cycling, electrical stimulation, or both, on thigh muscle volume and stimulated muscle strength in a small RCT in 30 children with SCI. Participants were randomly assigned to one of three interventions: FESC, passive cycling (PC), and noncycling, electrically stimulated exercise (ES). Each group exercised for1 hour, three times per week for 6 months at home. Muscle volume data were complete for 24 children (8

FESC; 8 PC; 8 ES) and stimulated strength data for 27 children (9 per group). Per analyses of covariance, there were differences between groups ($p<0.05$) for quadriceps muscle volume and stimulated strength, with the ES group having greater changes in volume and the FESC group having greater changes in strength. Although quadriceps strengthening for the ES group increased ($p=0.024$), a corrected value ($p=0.0167$) was needed to reach statistical significance. Other study limitations include missing data (that is, poor quality MRIs, failure to return for follow-up strength testing), and lack of consideration to the stage of maturation of the participants.

Lauer and colleagues (2011) conducted an RCT to determine the effect of cycling and/or electrical stimulation on hip and knee bone mineral density (BMD) in children with SCI. Participants were randomized to one of three interventions: FESC, PC, and non-cycling ES. Each group exercised for 1 hour, 3 times per week for 6 months at home. The hip, distal femur and proximal tibia BMD were examined via dual-energy X-ray absorptiometry (DXA) pre- and post-intervention. The FESC group exhibited increases in hip, distal femur and proximal tibia BMD of 32.4%, 6.62% and 10.3%, respectively; however, there were no significant differences between groups over time. Further study is needed with a larger sample size to determine the net health benefit of FESC for children with SCI.

A systematic review of the literature on the prevention and treatment of osteoporosis after spinal cord injury was published in 2018 by Soleyman-Jahi and colleagues. The authors concluded that there was very low-quality evidence that low-intensity cycling (3 days per week) with FES provided a benefit for reducing BMD loss in individuals with chronic SCI. A similar systematic review in 2023 by Ibitoye and colleagues found mixed results in terms of the effect of FES cycling on lower limb BMD. Several studies reported improvements in BMD in the proximal tibia, distal femur and lumbar spine. However, more studies found that FES cycling showed insignificant or partial improvement in BMD or had no influence at all.

In addition, FES cycle training has been proposed as a means to reduce cardiorespiratory and musculoskeletal stress to minimize the health risks associated with inactivity and lower extremity paralysis after SCI. The peer-reviewed published literature mainly consists of case series and non-randomized studies (Berry, 2009; Faghri, 1992) investigating cardiorespiratory responses and training effects of FESC in individuals with SCI. One small RCT by Johnston and colleagues (2009) examined the cardiorespiratory/vascular effects of cycling with and without FES in children ages 5 to 13 years with SCI (n=30) with injury levels from C4 to T11. Children were randomly assigned to 1 of 3 groups: FESC, passive leg cycling, or a non-cycling control group receiving electrical stimulation therapy. The children exercised at home for 1 hour three times per week for 6 months with parental supervision. The investigators reported no difference between groups ($p>0.05$) after 6 months of exercise when comparing pre- and post-therapy values for oxygen update, resting heart rate, forced vital capacity, and a fasting lipid panel. Although no significant safety issues have been identified with use of FES ergometer cycling, to date, the FDA's summary of safety and effectiveness for FES cycle ergometers do not indicate the devices have been cleared for use to prevent secondary dysfunction such as alterations in cardiovascular function, or to promote cardiovascular conditioning, associated with damage to motor nerve pathways in individuals with SCI and other neurological disorders affecting the lower extremities.

FES Devices to Promote Ambulation

Parastep I System

The Parastep device has been evaluated in uncontrolled case series; no controlled studies were identified. The largest series was conducted by Chaplin and colleagues (1996) who reported on the ambulation outcomes using the device in 91 individuals. A total of 84 of the 91 individuals (92%) were able to take steps and of these, 31 of the 91 individuals (34%) were able to eventually ambulate without assistance from another person. Duration of use was not reported.

Several publications from the 1990s evaluated the same group of 13 to 15 individuals (Guest, 1997; Jacobs 1997; Nash, 1997; Needham-Shropshire, 1997). Many of the outcomes reported were physiologic outcomes such as oxygen uptake and arterial inflow volume and evaluations of the Parastep device were performed immediately following initial training or after a short follow-up period. There are limited data regarding whether individuals remain compliant and committed with long-term use. Brissot and colleagues (2000) reported independent ambulation was achieved in 13 of 15 individuals, with 2 individuals withdrawing from the study. In the home setting, 5 of the 13 individuals continued using the device for physical fitness, but none used it for ambulation.

In summary, studies of the Parastep FES device used for ambulation demonstrate the device is associated with improvements in the intermediate outcomes of a variety of physiologic outcomes. However, there is inadequate data to show that these benefits exceed those offered by non-functional (passive) stimulation approaches. While device users can stand and walk short distances, there is inadequate data to show whether this results in clinically significant improvements in activities of daily living, and inadequate results to demonstrate that individuals consistently use the device over the long term. In addition, FES can expose the subject to significant risks such as falls, sprains and bone fractures.

Other FES Devices to Restore Ambulation

FES has also been investigated using IM electrodes. Daly and colleagues (2011) conducted an RCT evaluating a multimodal gait training protocol, with or without FES, to improve volitional walking in individuals with persistent (> 6 months) dyscoordinated gait following stroke. A total of 53 subjects were randomized to receive FES with IM electrodes (FES-IM) or No-FES. The primary outcome was the Gait Assessment and Intervention Tool (G.A.I.T.) of coordinated movement components. The G.A.I.T. showed an additive advantage with FES-IM versus No-FES (parameter statistic 1.10; $p=0.045$; 95% confidence interval [CI], 0.023-2.179) at the end of training. For both FES-IM and No-FES, a within-group, pre-and post-treatment gain was present for all measures ($p<0.05$), and a continued benefit from mid- to post-treatment ($p<0.05$) was present. For FES-IM, recovered coordinated gait persisted at 6-month follow-up but not for No-FES. Limitations of the study include a 17% dropout rate and short-term follow-up (12 weeks). Moreover, FES-IM is an invasive procedure that uses a research stimulation system, which is not yet clinically available. Implementing the FES-IM in clinical practice would involve an outpatient surgical procedure and the FES technology.

A 2019 systematic review by Shariat and colleagues identified two RCTs comparing cycling with FES to cycling in individuals post-stroke. A meta-analysis of the two trials found statistically significantly better improvement in balance when FES was added to a cycling intervention compared with cycling alone. However, neither of the individual RCTs (Bauer 2015; Lee 2013) reported statistically significantly better outcomes (e.g., 6-minute walk test, functional ambulation scale) when FES was added to a cycling intervention.

Khamis and colleagues (2018) conducted a systematic review examining the evidence for use of surface FES to improve walking ability and gait deviations in children with cerebral palsy. A total of 15 studies (n=151 children), including 1 randomized controlled trial, 2 non-randomized controlled trials, 5 single-subject designs, 1 cross-over design, 3 case series, 2 case studies, and 1 exploratory design study were included in the analysis. Six studies included a control group, with five matched control studies and three healthy control groups. The most common FES device stimulated the dorsiflexors muscles with a positive orthotic effect, improved dorsiflexion during the swing phase and enhanced the foot contact pattern. A small positive effect was found for knee extensors stimulation facilitating knee extension during the stance phase and for hip abductors stimulation improving frontal plane knee alignment. There was no evidence to support the use of plantar flexors stimulation in correcting gait deviations and scarce evidence of any retention effect. The investigators concluded that FES should be evaluated in randomized studies with larger populations to determine the orthotic and therapeutic effect of FES to improve gait in individuals with cerebral palsy.

A meta-analysis of the data from nine randomized controlled trials that examined the effect of FES on gait parameters in children with cerebral palsy was conducted by Zhu and colleagues (2022). A total of 282 children were included, 142 in the FES treatment group and 140 in the group receiving other treatment or physical therapy. Results showed that FES significantly increased the walking speed and step length of children with cerebral palsy. However, most of the studies were single-blind trials which have a high risk of bias. The authors concluded that more research and larger studies are needed to support the findings.

FES to Activate Muscles of Upper or Lower Limbs to Produce Functional Movement Patterns

Upper Limb

Several systematic reviews have evaluated the effect of upper limb FES, given in combination with standard care, on functional outcomes. Gus and Ran (2016) included 15 RCTs examining shoulder subluxation, pain, upper arm motor function, daily function, and quality of life in individuals post-stroke. On meta-analysis, a significant difference was found in shoulder subluxation between the FES group and the placebo group, but only if FES was applied early after stroke; however, FES therapy did not reduce shoulder pain or improve upper arm motor function, daily function, and quality of life at any other time after stroke.

In a meta-analysis of 20 studies, Eraifej and colleagues (2017) did not find a significant benefit of FES for objective activities of daily living measures in 6 studies (standardized mean difference [SMD] 0.64; 95% CI, -0.02 to 1.30; n=67 FES participants). Only 3 studies showed a significant benefit of FES on activities of daily living when initiated within 2 months post-stroke (SMD 1.24; CI, 0.46 to 2.03; n=32 FES participants). In 3 studies where FES was initiated more than 1 year after stroke, no significant activities of daily living improvements were seen (SMD -0.10; CI, -0.59 to 0.38; n=35 FES participants). Limitations of the evaluable studies included "very low quality evidence in all analyses due to heterogeneity, low participant numbers and lack of blinding."

Among the RCTs evaluating FES in upper limbs, Chan and colleagues published a study in 2009 evaluating 20 individuals, 6 months after the onset of stroke to receive 15 training sessions of stretching activities, FES with bilateral tasks, and occupational therapy treatment. The outcome measures included a Functional Test for the Hemiplegic Upper Extremity (FTHUE), Fugl-Meyer Assessment (FMA), grip power, forward reaching distance, active range of motion of wrist extension, Functional Independence Measure, and Modified Ashworth Scale. After 15 training sessions, the FES group had significant improvement in FMA (p=0.039), FTHUE (p=0.001), and active range of motion of wrist extension (p=0.020) when compared with the control group. The authors concluded that bilateral upper limb training with FES could be an effective method for upper limb rehabilitation of post-stroke individuals after 15 training sessions. This trial is limited in its application by the small sample size, short duration of treatment, and lack of long-term outcome measures.

An RCT by Koyuncu and colleagues (2010) evaluated FES for the treatment of shoulder subluxation and pain in individuals with hemiplegia. All 50 participants received conventional rehabilitation methods and the study group was additionally applied FES to the supraspinatus and posterior deltoid muscles (hemiparetic side) for 1 hour, 5 times a day, for 4 weeks. The shoulder pain of all participants during resting, passive range of motion (PROM) and active range of motion (AROM) was measured with the visual analog scale (VAS). Shoulder subluxation levels were compared before and after physical therapy and the rehabilitation program using millimetric measurements on anteroposterior shoulder X-rays. Comparison of the resting AROM to the PROM VAS showed no significant difference between the groups. There was a significant difference between the 2 groups for the amount of change in shoulder subluxation and subluxation levels ($p<0.001$; $p<0.05$, respectively) in the study group but not in the control group. The small sample population and short-term follow-up are limitations of this study.

Harvey and colleagues (2016) published a multicenter RCT evaluating the effect of adding an intensive task-specific hand-training program involving FES to a combination of usual care plus three 15-minute sessions per week of one-to-one hand therapy in 70 individuals with C2 to T1 motor complete or incomplete tetraplegia within 6 months of injury. Control participants received usual care consisting of functional hand activities and did not receive the intensive task-specific hand-training program with FES. The primary outcome was the modified Action Research Arm Test (m-ARAT) of the target hand (reflecting arm and hand function), which was assessed 11 weeks after randomization. Secondary outcomes were measured at 11 and 26 weeks. A total of 66 (94%) participants completed the post-intervention assessment and were included in the primary ITT analysis. The m-ARAT score for experimental and control participants at the post-intervention assessment was 36.5 points (standard deviation [SD] 16.0) and 33.2 points (SD 17.5), respectively, with an adjusted mean between-group difference of 0.9 points (95% CI, -4.1-5.9). The investigators concluded that adding an intensive task-specific hand-training program involving FES to a combination of usual care plus three 15-minute sessions per week of one-to-one hand therapy did not improve hand function in people with sub-acute tetraplegia.

Lower Limb: 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 stroke or nerve injury. Treatment typically consists of an ankle foot orthosis or another type of limb brace. These devices are designed to provide stability. In contrast, FES devices are designed to improve function by enabling the foot to be raised during the swing phase of ambulation.

Prenton and colleagues (2018) performed a meta-analysis of seven RCTs comparing the therapeutic effects of FES versus ankle-foot orthoses (AFOs) for foot drop of central nervous system origin. All study participants had unilateral foot drop. A meta-analysis of walking speed at the final data assessment in six of the seven trials (number of participants=437) did not find a statistically significant difference between the FES and AFO groups (mean difference [MD] 0.02; 95% CI, -0.03-0.06). A sensitivity analysis excluding the three trials with high risk of bias had similar findings.

Another meta-analysis (Miller, 2017) focused on FES in individuals with multiple sclerosis-associated foot drop. A total of 19 observational (1 case-control, 8 interrupted time series) or experimental (1 randomized controlled trial, 1 randomized crossover trial, and 8 non-randomized control trials) studies (n=490 participants) were identified and rated as "moderate or weak" in design; all studies were rated "weak" for blinding. Sample numbers in most studies were generally small and ranged from 2 participants to 39 participants. One retrospective observational study included data from 153 participants. Meta-analyses of the short walk tests showed a significant initial and ongoing orthotic effect up to 20 weeks (t=2.14 [p=0.016]; t=2.81 [p=0.003], respectively). Walking speed increased by a mean of .05 m/s for the initial orthotic effect and .08 m/s (11.3%) and for the ongoing orthotic effect. Six studies (n=244 participants) were included in the meta-analysis for the therapeutic effect of FES on gait speed. Pooled data analysis found no change in gait speed (no therapeutic effect) in short walking performance tests (t=0.03; p=0.487) with FES. There was a small non-significant increase in gait speed of .02 m/s (3.3%) for the initial orthotic effect (n=89 participants) (t=0.57; p=0.286) and a small non-significant increase of .04 m/s (6.2%) for ongoing continued orthotic effect of up to 20 weeks (n=81 participants) (t=0.94; p=0.174) with FES. Only 3 studies (n=61 participants) included data to evaluate the therapeutic effect of FES on gait speed in long walking performance tests up to 20 weeks. There was a 10.3% increase in walking speed noted; however, this was nonsignificant (t=1.34; p=0.091). Limitations of this meta-analysis include the low methodologic quality and contradictory results identified across the studies. Most articles did not report on the type of multiple sclerosis, which may limit the external validity of the findings. Only 1 interventional study reported on treatment effects beyond 24 weeks; therefore, the results are only applicable to short or moderate follow-up

outcomes.

Kluding and colleagues (2013) conducted a multicenter, single-blind RCT comparing the NESS L300 Foot Drop System to an AFO for drop foot among individuals at least 3 months after stroke with gait speed ≤ 0.8 meters/second (m/s). A total of 197 participants (61.14 ± 11.61 years of age; time after stroke 4.55 ± 4.72 years) were randomized to 30 weeks of either NESS L300 or a standard AFO. A total of 8 dose-matched physical therapy sessions were provided to both groups during the first 6 weeks of the trial. There was significant improvement reported within both groups from baseline to 30 weeks in comfortable gait speed (95% CI for mean change, 0.11-0.17 m/s for NESS L300 and 0.12-0.18 m/s for AFO), fast gait speed, and the secondary outcome of user satisfaction with the NESS L300 device; however, the authors noted that "…poor compliance with AFOs has been reported in people with foot drop and may have been a factor leading to the lack of adequate use of AFOs in many of the participants at enrollment into the study." Despite improvements reported in gait speed and user satisfaction with the NESS L300 device within both groups, the study did not demonstrate greater improvement in gait speed in participants randomized to the NESS L300 group, as no significant differences in gait speed were found in the between-group comparison analysis. O'Dell and colleagues (2014) performed a secondary analysis of data from this study. Comfortable gait speed was assessed in 99 individuals from the NESS L300 group at 6, 12, 30, 36, and 42 weeks, with and without use of the foot drop stimulator. A responder was defined as achieving a minimal clinically important difference of 0.1 m/s on the 10MWT or advancing by at least 1 Perry Ambulation Category. Noncompleters were classified as nonresponders. A total of 70% of participants completed the assessments at 42 weeks and 67% of participants were classified as responders. Of the 32 participants who were classified as nonresponders, 2 were nonresponders and 30 were noncompleters. The study did not report the percentage of participants in the conventional AFO group who were classified as responders at 30 weeks. A total of 160 adverse events were reported, 92% were classified as mild, with 50% and 27% attributed to reversible skin issues and to falls, respectively.

Lower Limb: Post-Stroke/Hemiplegia or Post-SCI

Kafri and Laufer (2015) systematically reviewed the literature to assess the carryover effects of lower extremity FES motor performance following stroke. A total of 16 randomized and non-randomized trials met the inclusion criteria. The therapeutic effects of FES were measured at > 3-6 months in the chronic post-stroke phase. In 11 studies, the overall findings indicated "clinically important" increases in speed. The positive therapeutic effects of FES were reported for other mobility-related variables including walking independence (2 studies), walking distance (3 studies), stair negotiation (2 studies), and muscle strength and voluntary range of motion (9 studies). The therapeutic effect of FES on balance did not demonstrate any clear patterns of response (5 studies). The effects of FES on spasticity indicated a positive effect in the sub-acute (1 study) and chronic phases (3 studies) of stroke; however, the investigators questioned whether the therapeutic effects specific to the FES intervention "…are due primarily to the electrical stimulation delivered by the FES…or whether they can be achieved by any means that enable functional movement." Contradictory findings were identified in the training studies regarding the superiority of FES with training relative to control training without FES. No superior effects were reported when FES was used as an alternative to ankle-foot orthosis (AFO) (4 studies). Although some positive effects of FES training were reported, the results were inconsistent when FES was compared to matched treatments that did not incorporate FES. The investigators concluded it was "difficult to determine optimal treatment protocols due to inconsistent and wide ranging outcome measures, varying exposures to FES, and the different FES parameters used." Additional well-designed, controlled studies are required to substantiate the therapeutic effects of FES to promote gait performance and lower extremity motor recovery following stroke.

Previously, Pereira and colleagues (2012) conducted a systematic review on the effectiveness of FES in improving lower extremity function in chronic stroke. Studies included in the review were 1) randomized controlled trials; 2) ≥ 50% of the study population had sustained a stroke; 3) the mean time since stroke was ≥ 6 months; 4) FES or neuromuscular electrical stimulation (NMES) was compared to other interventions or a control group; and 5) functional lower extremity outcomes were assessed. A total of seven randomized controlled trials including a pooled sample size of 231 participants met inclusion criteria. Pooled analysis revealed a small but significant treatment effect of FES (0.379 ± 0.152; 95% CI, 0.081-0.677; p=0.013) on a 6-minute walk test. The authors concluded that FES may be an effective intervention in the chronic phase post stroke, however, "its therapeutic value in improving lower extremity function and superiority over other gait training approaches remains unclear."

Additional studies have evaluated the use of FES to reduce ankle spasticity or improve muscle strength, walking ability (that is, gait performance) and metabolic responses in the management of individuals with post-stroke hemiparesis (Cheng 2010; Embry, 2010;Sabut, 2010a; Sabut, 2010b; Sheffler, 2013; Springer, 2012; Springer, 2013). Limitations of these studies include, but are not limited to, small participant populations, lack of blinding to treatment, and short-term follow-up.

Other studies have investigated the effects of the FES cycling on lower extremity spasticity in individuals with SCI. In a systematic review, Alashram and colleagues (2022) evaluated 2 RCTs, 2 cohort studies and 6 pilot studies. The results showed some evidence for beneficial effects of FES cycling on the spasticity of lower extremities. However, the majority of the studies were of low methodological quality and included small numbers of participants, and all involved lack of blinding of participants and therapists. In a similar systematic review with meta-analysis, Fang and colleagues (2021) examined 8 studies that included 99 individuals with SCI. Spasticity was found to decrease after FES cycling, however most of the studies were not RCTs and included small numbers of individuals. The authors concluded that future high quality RCT studies are needed to provide stronger evidence of the effect of FES on spasticity.

WalkAide

Stein and colleagues (2010) compared the orthotic and therapeutic effects of the WalkAide (Innovative Neurotronics, Austin, TX) stimulator on walking performance of subjects with chronic nonprogressive (n=41, with stroke, SCI, head injury, or cerebral palsy) and progressive (n=32, with secondary progressive multiple sclerosis or familial spastic paraparesis) disorders resulting in foot drop. After 3 months of FES use, the nonprogressive and progressive groups had a similar, significant orthotic effect (5.0% and 5.7%, respectively; p<0.003, percentage change in mean values) and therapeutic effect with FES off (17.8% and 9.1%, respectively; p<0.005) on figure-8 walking speed. The therapeutic effect on figure-8 speed diverged later between both groups to 28.0% (p<0.001) and 7.9% at 11 months. While the nonprogressive group continued to increase speed with and without stimulation, a plateau of gait speed with a tendency to a decline in speed occurred in the progressive group as a whole. The authors suggested that the decrease in walking speed may have resulted from weakening of other muscle groups that were not being stimulated. There was a significant difference in the use of the WalkAide by the progressive group compared to the nonprogressive group (p=0.037). The study limitations include the small heterogeneous participant population, lack of randomization and a control group, and short-term follow-up.

Bethoux and colleagues (2014) published an industry-sponsored RCT comparing use of the WalkAide with an AFO that included 495 Medicare-eligible individuals who were at least 6 months post stroke. 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. There were seven 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 of the study, and the WalkAide device was noninferior to the AFO on the primary outcome measures. Only the WalkAide group showed significant improvements from baseline to 6 months on several secondary outcome measures; however, there were no significant between-group differences for any of the outcomes.

Threshold Electrical Stimulation

TES as a treatment of scoliosis was widely investigated in the 1980s. However, retrospective studies suggested that the outcomes associated with electrical stimulation were not significantly different than the natural history of scoliosis. Nachemson and Peterson (1995) published the results of a prospective study comparing the outcomes of bracing and electrical stimulation to those of untreated individuals. While those treated with bracing reported improved results, those treated with electrical stimulation did not. Since that time many scoliosis experts have abandoned electrical stimulation.

Studies conflict as to whether TES shows net benefit as a treatment for cerebral palsy and other motor disorders. One randomized controlled trial of individuals with cerebral palsy, who had previously undergone selective rhizotomy, appeared to depict a net improvement in motor function from TES (Steinbock, 1997); however, other randomized controlled trials using TES in individuals with cerebral palsy failed to show any objective clinical benefit (Dali, 2002; Kerr, 2006; van der Linden, 2003). Cauraugh and colleagues (2010) conducted a systematic review and meta-analysis using the International Classification of Functioning to determine the summary effect of electrical stimulation on impairment and activity limitations relevant to gait problems of children with cerebral palsy. The authors cited reservation about recommending electrical stimulation as an efficacious intervention for individuals with cerebral palsy. Outside of the laboratory-testing experiments, “no quantitative, functional immediate or longitudinal effects beyond the testing situations were reported in the studies. Thus, long-term effects of various types of electrical stimulation on gait challenges in children with cerebral palsy would advance our understanding.”

Background/Overview

FES attempts to replace stimuli from destroyed nerve pathways with computer-controlled sequential electrical stimulation of muscles to enable individuals with SCI or stroke to function independently, or at least maintain healthy muscle tone and strength. This is in contrast to the use of neuromuscular stimulation for disuse atrophy when the nerve supply to the muscle is intact.

FES Devices Used for General Rehabilitation

The ERGYS (Therapeutic Alliances Inc., Fairborn, Ohio) is a medical device categorized as a powered muscle stimulator by the U.S. Food and Drug Administration (FDA). Computer generated, low-level electrical pulses transmitted through surface electrodes cause coordinated contractions of the large muscles of the legs. Sensors located in the ERGYS provide continuous feedback to a computer which controls the sequence of muscle contractions as well as the resistance to pedaling. The RT300 device (Restorative Therapies, Inc., Baltimore, MD) received FDA 510(k) marketing clearance on June 27, 2005 as a FES cycle ergometer device with models designed for pediatric (ages 4 to 12 years) and adult use (that is, RT300 Leg, RT300 Leg and Arm, RT300 Arm, RT300-SP for children). These Class II devices are powered muscle stimulators for general rehabilitation for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation and maintaining or increasing range of motion. On April 4, 2011, the RT600 FES stepper ergometer received 510(k) clearance as a substantially equivalent device to the predicate RT300 FES device for use in individuals 12 years of age and older.

FES Devices Used for Ambulation

The Parastep Ambulation System (Parastep™ I System, Sigmedics, Inc., Fairborn, OH) is an ambulation FES device approved by the FDA in 1994. The premarket approval (PMA) document stated the Parastep-I device:

> Enables appropriately selected skeletally mature spinal cord injured individuals (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.

According to the device manufacturer, the system is designed to provide up to six channels of stimulation, stimulating up to three muscle groups on the side of each leg. Some individuals may require only four channels of stimulation to stand and ambulate, where electrical stimulation is directed to four electrodes on each lower extremity. Stimulation of the quadriceps muscles results in knee extension, enabling the user to stand. Stimulation of the peroneal nerve in the lower extremity initiates a triple-flexion reflex response, resulting in contraction of muscles to flex the hip, knee, and ankle, which lifts the foot off the floor. Subsequent quadriceps stimulation extends the knee in preparation for heel-strike and weight bearing. When six channels of stimulation are used, electrical stimulation is directed to the previously mentioned sites and to two additional electrodes on each hip. Stimulation of gluteal muscles extends the hips, contributing to stability while standing and taking steps. In addition, the individual uses a walker or elbow-support crutches for further support. The electrical impulses are controlled by a computer microchip attached to the individual’s belt that synchronizes and distributes the signals. Finally, there is a finger-controlled switch that permits activation of the stepping device by the individual.

Other devices include a reciprocating gait orthosis (RGO) with electrical stimulation. The orthosis used is a rather cumbersome hip-knee-ankle-foot device linked together with a cable at the hip joint. FES has been adapted to use with the RGO as a hybrid device.

FES Devices for Other Indications

Devices used to treat foot drop include the WalkAide, the NESS L300 Foot Drop System (Bioness, Inc, Valencia, CA), and the ODFS Dropped Foot Stimulator/ODFS Pace. The devices consist of a gait sensor, leg cuff and hand held control. When the heel lifts, signals from the gait sensor are sent to the stimulation unit in the leg cuff that stimulates the common peroneal nerve that innervates the tibialis anterior muscles, which in turn lifts the foot while walking. The WalkAide device first received 510(k) marketing clearance from the FDA in the 1990s with subsequent upgrades to the system. The Bioness NESS L300 received 510(k) marketing clearance in July 2006. The ODFS Dropped Foot Stimulator received 510(k) marketing clearance on July 15, 2005. The ODFS Pace received 510(k) clearance as a substantially equivalent device on March 30, 2011. The FDA summaries for these devices state that they are intended for use in individuals with drop foot by assisting with ankle dorsiflexion during the swing phase of gait.

There are multiple FDA 510K marketing clearances for functional neuromuscular stimulators for use on the hand and forearm. These include the NESS Neuromuscular Electrical Stimulation Systems Handmaster (K010837, K012823, and K031900). The FDA has also approved the NESS System Powered Muscle Stimulator (K022776) for use at sites on the limbs other than the hand. The NESS Systems are portable, one-channel electrical neuromuscular stimulators. The stimulators are powered by rechargeable batteries. Surface electrodes are held on to the limb by a splint. Electrical stimulation is delivered to the muscles through the surface electrodes. The NESS H200 Hand Rehabilitation System is designed to stimulate the extensor and flexor muscle of the forearm as well as the ulnar muscle of the hand. The stimulation is intended to provide hand active range of motion and hand function for individuals with upper limb paralysis due to C5 SCI or hemiplegia due to stroke.

TES

TES or therapeutic electrical stimulation involves the delivery of low intensity electrical stimulation (typically at night) and has been investigated as a treatment of scoliosis. Stimulation is applied to the convex side of the curvature in order to evoke muscle

contractions causing curvature correction. Electrical stimulation may be one component of an overall non-surgical treatment program for scoliosis. For example, the Scoliosis Treatment Recovery System, which includes the Copes Scoliosis Dynamic Brace, also includes electrical stimulation as part of the treatment program. For individuals with cerebral palsy, threshold electrical stimulation is designed to increase muscle strength and joint mobility leading to improved voluntary motor function.

Definitions

Cerebral palsy: A persistent qualitative motor disorder appearing before the age of 3 years due to non-progressive damage to the brain.

Disuse atrophy: A wasting or loss of size of a part of the body because of disease or other influences.

Functional electrical stimulation (FES): A rehabilitation technique where a low-level electrical current is applied to muscles of a neurologically impaired individual in an attempt to replace stimuli from destroyed nerve pathways and enhance that person's ability to maintain healthy muscle tone and strength to function independently.

Scoliosis: A congenital lateral curvature of the spine.

Threshold (or therapeutic) electrical stimulation (TES): A form of low-intensity electrical stimulation that attempts to strengthen muscles weakened by non-use.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

Functional Electrical Stimulators
When services are Investigational and Not Medically Necessary:

HCPCS

E0764	Functional neuromuscular stimulator, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified [e.g., NESS L300, WalkAide device, NESS H200]

ICD-10 Diagnosis

	All diagnoses

Threshold Electrical Stimulators
When services are Investigational and Not Medically Necessary:

HCPCS

	For the following codes **when specified as a threshold electrical stimulator device**:
E0745	Neuromuscular stimulator, electronic shock unit
E1399	Durable medical equipment, miscellaneous

ICD-10 Diagnosis

G80.0-G80.9	Cerebral palsy
G81.00-G82.54	Hemiplegia and hemiparesis, paraplegia and quadriplegia
G83.0-G83.34	Diplegia, monoplegia of limbs
G83.5	Locked-in state
G83.81-G83.9	Other specified paralytic syndromes, paralytic syndrome unspecified
I69.031-I69.069	Monoplegia of limb, hemiplegia and hemiparesis, other paralytic syndrome following nontraumatic subarachnoid hemorrhage
I69.131-I69.169	Monoplegia of limb, hemiplegia and hemiparesis, other paralytic syndrome following nontraumatic intracerebral hemorrhage
I69.231-I69.269	Monoplegia of limb, hemiplegia and hemiparesis, other paralytic syndrome following nontraumatic intracranial hemorrhage
I69.331-I69.369	Monoplegia of limb, hemiplegia and hemiparesis, other paralytic syndrome following cerebral infarction
I69.831-I69.869	Monoplegia of limb, hemiplegia and hemiparesis, other paralytic syndrome following other cerebrovascular disease
I69.931-I69.969	Monoplegia of limb, hemiplegia and hemiparesis, other paralytic syndrome following unspecified cerebrovascular disease
M40.00-M40.57	Kyphosis and lordosis
M41.00-M43.9	Scoliosis, spinal osteochondrosis, other deforming dorsopathies
R26.0-R26.9	Abnormalities of gait and mobility
S14.101S-S14.159S	Other and unspecified injuries of cervical spinal cord, sequela [by level; includes codes S14.101S, S14.102S, S14.103S, S14.104S, S14.105S, S14.106S, S14.107S, S14.108S, S14.109S, S14.111S, S14.112S, S14.113S, S14.114S, S14.115S, S14.116S, S14.117S, S14.118S, S14.119S, S14.121S, S14.122S, S14.123S, S14.124S, S14.125S, S14.126S, S14.127S, S14.128S, S14.129S, S14.131S, S14.132S, S14.133S, S14.134S, S14.135S, S14.136S, S14.137S, S14.138S, S14.139S, S14.141S, S14.142S, S14.143S, S14.144S, S14.145S, S14.146S, S14.147S, S14.148S, S14.149S, S14.151S, S14.152S, S14.153S, S14.154S, S14.155S, S14.156S, S14.157S, S14.158S, S14.159S]
S24.101S-S24.159S	Other and unspecified injuries of thoracic spinal cord, sequela [by level, includes codes S24.101S, S24.102S, S24.103S, S24.104S, S24.109S, S24.111S, S24.112S, S24.113S, S24.114S, S24.119S, S24.131S, S24.132S, S24.133S, S24.134S, S24.139S, S24.141S, S24.142S, S24.143S, S24.144S, S24.149S, S24.151S, S24.152S, S24.153S, S24.154S, S24.159S]

S34.101S-S34.139S	Other and unspecified injury of lumbar and sacral spinal cord, sequela [by level, includes codes S34.101S, S34.102S, S34.103S, S34.104S, S34.105S, S34.109S, S34.111S, S34.112S, S34.113S, S34.114S, S34.115S, S34.119S, S34.121S, S34.122S, S34.123S, S34.124S, S34.125S, S34.129S, S34.131S, S34.132S, S34.139S]

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Index

NESS H200 System
NESS L300 Foot Drop System
NESS L300 Plus System
ODFS-Odstock Dropped Foot Stimulator
ODFS Pace
Parastep I System
RT300 FES Cycle Ergometer
RT300/300S Systems
RT300-SL Therapy Rehabilitation System
RT600 Step and Stand Rehabilitation Therapy System
WalkAide

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised formatting of Position Statement. Revised Rationale, References and Websites for Additional Information sections.
Reviewed	02/16/2023	MPTAC review. References were updated.
Reviewed	02/17/2022	MPTAC review. References were updated.
Revised	02/11/2021	MPTAC review. The Position Statements were reformatted for clarification with no change to stance. References were updated.
Reviewed	02/20/2020	MPTAC review. Updated Description/Scope, Rationale, References, and Websites for Additional Information sections.
Reviewed	03/21/2019	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	05/03/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	05/04/2017	MPTAC review. Updated formatting in Position Statement section. Updated Rationale, Background, References, Websites for Additional Information, and Index sections.
Reviewed	05/05/2016	MPTAC review. Minor format changes to the Rationale section. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Rationale, References, and Websites for Additional information sections. Format changes throughout document.
Reviewed	05/15/2014	MPTAC review. Minor format changes. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	05/09/2013	MPTAC review. Minor format changes. Updated Description, Rationale, References, Websites for Additional Information, and Index.
Reviewed	05/10/2012	MPTAC review. Updated Description, Rationale, Background, Coding, References, Websites for Additional Information and Index.
Reviewed	05/19/2011	MPTAC review. Updated Rationale, References and Websites for Additional Information.
	08/19/2010	MPTAC recommendation to revise text in the Background/Discussion section, *Functional Electrical Stimulation: Devices Used for Ambulation,* that describes the stimulation of the peroneal nerve when the individual utilizes the Parastep-I device.
Reviewed	05/13/2010	MPTAC review. Updated Rationale, including FES for upper extremity conditions/chronic post stroke hemiparesis and foot drop, multiple sclerosis and cerebral palsy. Updated References and Index.
Revised	05/21/2009	MPTAC review. Clarified investigational and not medically statement for functional electrical stimulation when used to activate muscles of the upper limb to produce functional movement patterns, adding lower limb to the current statement; updated device names. Revised Description, Rationale, Discussion, and Definitions. Updated References and Index with device information.
	01/01/2009	Updated Coding section with 01/01/2009 HCPCS changes.
Reviewed	05/15/2008	MPTAC review. Description and References updated.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Revised	05/17/2007	MPTAC review. Added FES of the upper limb to produce functional movement patterns as investigational/not medically necessary. Coding updated; removed HCPCS K0600 deleted 12/31/2005.
Reviewed	06/08/2006	MPTAC review. References and Coding updated.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes.
	11/22/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization. Addition of language addressing ERGYS.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.	04/27/2004	DME.00022	Neuromuscular Stimulation: Functional Electrical Stimulation (FES); Threshold Electrical Stimulation (TES)
WellPoint Health Networks, Inc.	12/02/2004	9.07.01	Transcutaneous Stimulation for the Treatment of Scoliosis, Cerebral Palsy and other Motor Disorders

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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 eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.