ELECTRICAL STIMULATION FOR THE TREATMENT OF PAIN AND MUSCLE REHABILITATION

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Related Medical Policies:
- Transcutaneous Electrical Nerve Stimulation (TENS) for the Treatment of Nausea and Vomiting
- Related Coverage Determination Guidelines: None

COVERAGE RATIONALE

Functional electrical stimulation (FES), a form of neuromuscular electrical stimulation (such as Parastep I), is proven for rehabilitation in persons with paralyzed lower limbs due to spinal cord injury (SCI) with all of the following characteristics:
- Intact lower motor units (L1 and below) (both muscle and peripheral nerves)
- 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;
- Demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
- Possess high motivation, commitment and cognitive ability to use such devices for walking;
- Able to transfer independently and demonstrate independent standing tolerance for at least 3 minutes;
- Demonstrate hand and finger function to manipulate controls;
- Post recovery from spinal cord injury and restorative surgery of at least 6-months;
- No hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis

Functional electrical stimulation (such as ERGYS, RT300 or ODFS Dropped Foot Stimulator) is unproven for the treatment of disuse muscle atrophy in persons with spinal cord injury (who do not meet the requirements above) or multiple sclerosis.

Further studies are needed to confirm that functional electrical stimulation promotes bone remineralization and prevents or reverses muscle atrophy. Only a few studies have looked at FES as a modality of treatment of multiple sclerosis, and the results are limited and conflicting regarding whether FES improves treatment outcomes in multiple sclerosis when offered in addition to other rehabilitative treatment modalities.

Functional electrical stimulation (such as Walkaide, NESS L300 or ODFS Dropped Foot Stimulator) is unproven for the treatment of gait disorders (e.g., foot drop) of central neurologic origin including but not limited to stroke or multiple sclerosis.

There is insufficient evidence in the peer reviewed literature that use of functional electrical stimulation will improve health outcomes in patients with gait disorders. Published studies have included small heterogeneous patient populations, short-term follow-ups, and various treatment protocols, outcome measures, and FES devices. Only a few studies have looked at FES as a modality of treatment of multiple sclerosis, and the results are limited and conflicting regarding whether FES improves treatment outcomes in multiple sclerosis when offered in addition to other rehabilitative treatment modalities.

Neuromuscular electrical stimulation (NMES) is proven for:

A. Treatment of disuse muscle atrophy if:
   - The nerve supply to the muscle is intact; and
   - The disuse muscle atrophy is not of neurological origin but originates from conditions such as casting, splinting or contractures.

B. Treatment to improve wrist and finger function and prevent or correct shoulder subluxation in persons with partial paralysis following stroke

Neuromuscular electrical stimulation (NMES) is unproven for the treatment of neurologic, orthopedic (e.g., scoliosis) or other abnormalities including pain not listed as proven. Additionally, there is insufficient evidence for NMES for all other indications. There is insufficient evidence in the peer reviewed literature that use of electrical stimulation will improve health outcomes for the treatment of neurologic or orthopedic conditions other than those identified above as proven. Randomized, controlled trials are necessary to assess the durability of this procedure in comparison to other types of treatment.

Interferential therapy (IFT) is unproven for the treatment of musculoskeletal disorders or injuries, or stimulating healing of nonsurgical soft tissue injuries.

Interferential therapy is unproven to facilitate the healing of bone fractures.

There is insufficient evidence from the available studies to conclude that interferential therapy promotes healing of bone fractures. None of the double-blind, randomized, placebo-controlled studies reported a positive treatment effect of interferential therapy for bone fractures.

Pulsed electrical stimulation (PES) is unproven for the treatment of osteoarthritis.

There is insufficient evidence to conclude that PES provides health benefits to patients with osteoarthritis. Randomized, controlled trials are necessary to assess the durability of this procedure in comparison to other types of treatment.
Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS) is unproven for the treatment of pain. Evidence for the effectiveness of PSFS or PNFS based on controlled studies is lacking. Randomized controlled trials are needed to evaluate the efficacy of this treatment.

**Information Pertaining to Medical Necessity Review (When Applicable)**
The above indications apply to medical necessity review.

**BACKGROUND**

Electrical stimulators provide direct, alternating, pulsating and/or pulsed waveform forms of energy. The devices are used to exercise muscles, demonstrate a muscular response to stimulation of a nerve, relieve pain, relieve incontinence, and provide test measurements. Electrical stimulators may have controls for setting the pulse length, pulse repetition frequency, pulse amplitude, and triggering modes. Electrodes for such devices may be indwelling, transcutaneous implanted or surface.

**Functional electrical stimulation (FES), or therapeutic electrical stimulation (TES), attempts to prevent or reverse muscular atrophy and bone demineralization by stimulating paralyzed lower limbs to perform stationary exercise or standing and walking. Functional electrical stimulation has also been investigated as a way to improve gait disorders of hemiplegic patients. Although some paraplegics can walk extended distances using a functional electrical stimulator, this technology is not intended as a replacement for a wheelchair.** (Hayes, 2003)

It is designed to be used as part of a self-administered home-based rehabilitation program for the treatment of upper limb paralysis from hemiplegic stroke, traumatic brain injury or C5 to C6 spinal cord injury. The system contains a custom-fitted orthosis and a control unit. The control unit allows the user to adjust the stimulation intensity and training mode. Exercise sessions can be gradually increased to avoid muscle over-fatigue.

Parastep I is an electrical stimulation device for paraplegics. ERGYS is a powered muscle stimulator and RT300 is a FES cycle ergometer for relaxation of muscle spasms and prevention or retardation of disuse atrophy. Walkaide is a neuromuscular functional stimulator that stimulates the muscles that cause ankle dorsiflexion. NESS L300 provides ankle dorsiflexion in individuals with drop foot following an upper motor neuron injury or disease.

**Interferential therapy (IFT)** is a type of transcutaneous electrotherapy. Two slightly different, medium frequency alternating currents are simultaneously applied to the affected area through electrodes. Superposition or interference between the two currents causes the combined electrical current to rise and fall.

**Neuromuscular electrical stimulation (NMES)** involves the use of transcutaneous application of electrical currents to cause muscle contractions. The goal of NMES is to promote reinnervation, to prevent or retard disuse atrophy, to relax muscle spasms, and to promote voluntary control of muscles in patients who have lost muscle function due to surgery, neurological injury, or disabling condition. (Hayes, 2008)

**Neuromuscular electrical stimulators (NMES) are divided into two broad categories: Therapeutic and Functional.**

**Therapeutic** electrical stimulation strengthens muscles weakened by disuse while functional electrical stimulation attempts to replace destroyed nerve pathways by electrical stimulation to the muscle in order to assist a functional movement.

**Functional** NMES is a method being developed to restore function to patients with damaged or destroyed nerve pathways through use of an orthotic device with
microprocessor controlled electrical neuromuscular stimulation.

**Pulsed electrical stimulation (PES)** is hypothesized to facilitate bone formation, cartilage repair, and alter inflammatory cell function. Some chondrocyte and osteoblast functions are mediated by electrical fields induced in the extracellular matrix by mechanical stresses. Electrostatic and electrodynamic fields may also alter cyclic adenosine monophosphate or DNA synthesis in cartilage and bone cells.

**Peripheral subcutaneous field stimulation (PSFS)**, also known as peripheral nerve field stimulation (PNFS), is a technique used when the field to be stimulated is not well defined by any one or two peripheral nerves. PSFS is not the same as spinal cord stimulation (SCS) or peripheral nerve stimulation (PNS). During PSFS, a stimulator device (i.e., electrode arrays) is implanted within the subcutaneous tissue over the painful area, not on or around identified neural structures (Abejon and Krames 2009).

**CLINICAL EVIDENCE**

**Functional electrical stimulation (FES)**

Hayes (2011) performed evidence review from six studies that evaluated FES for treatment of patients with multiple sclerosis. Some evidence from six clinical studies that were evaluated suggests that use of the WalkAide System or the ODFS Pace may improve walking speed; however, the results were conflicting. Some studies reported significant increases in walking speed with FES ranging from 7% to 14% compared with baseline, while others reported no significant clinical effect or increases in walking speeds. There was no evidence suggesting that the use of the FES device helped MS patient’s approximate normal walking speed. Overall, there was very limited evidence on the effect of FES on other patient-relevant, functional measures. For example, none of the studies evaluated whether FES enabled patients to walk up and down stairs, walk on uneven ground, perform side steps, or whether its use improved confidence while performing these various activities. The bulk of the evidence evaluated surrogate outcome measures, including gait and walking parameters, measured in highly controlled experimental settings, to predict functional status in everyday environments. Such results may not be of immediate clinical relevance to the patient, or may not translate directly to functional improvement in ADL or improvement in QOL. There was no available evidence regarding implantable FES devices. Since the studies were case series and poor-quality RCTs, the validity of the evidence is unclear. It was difficult to compare the study findings due to various limitations, such as considerable clinical and methodological heterogeneity across the available studies, the insufficient power of these small clinical trials to detect statistical differences between treatment groups, and the lack of blinding and placebo groups (although blinding and the use of adequate placebo groups were not always practical or feasible). In addition, few of the available studies discussed the magnitude of benefit of FES treatment or whether the therapy leads to meaningful improvements in health outcomes for patients with MS.

Future, well-designed, sufficiently powered RCTs with adequate follow-up are necessary to compare the use of FES with appropriate placebo controls, such as sham treatments, and establish the magnitude of benefit of FES devices. Future research should compare different applications of FES, including implanted or surface stimulation. Methods of independent assessment should be incorporated since adequate blinding is not always feasible for this technology. Additional well-designed studies are necessary to adequately assess the impact of FES on functional status with a particular emphasis on practical dimensions of ADL. Studies with a priori plans for subgroup analyses are also needed to determine the patient and disease characteristics that are associated with clinically relevant, successful outcomes.

A randomized, controlled trial examined coordination exercises, gait training, and treadmill training with and without FES using intramuscular electrodes in 32 patients after stroke (Daly, 2006). The group treated with FES using intramuscular electrodes demonstrated statistically significant greater gains for gait component execution and knee flexion coordination than the
control group. A trial of 43 subjects, who had undergone anterior cruciate ligament reconstruction were randomly assigned to receive or not receive FES as an adjunct treatment to improve quadriceps strength. The FES group demonstrated greater quadriceps strength at 12 weeks and higher levels of self-reported knee function at 12 and 16 weeks as compared to the group that did not receive FES (Fitzgerald, 2003).

Barrett et al. (2009) conducted a two-group randomized trial to assess the effects of single channel common peroneal nerve stimulation on objective aspects of gait relative to exercise therapy for people with chronic progressive multiple sclerosis (CPMS). Forty-four people with a diagnosis of CPMS and unilateral dropped foot completed the trial. Patients were randomly allocated to receive either FES (n=20) or a physiotherapy home exercise program (n=24) for 18 weeks. The exercise group showed a statistically significant increase in 10 m walking speed and distance walked in 3 min, relative to the FES group who showed no significant change in walking performance without stimulation. At each stage of the trial, the FES group performed to a significantly higher level with FES than without for the same outcome measures. The authors concluded that exercise may provide a greater training effect on walking speed and endurance than FES for people with CPMS. Additional studies are needed to investigate the combined therapeutic effects of FES and exercise for patients with MS.

Broekmans et al. (2011) conducted a randomized controlled study involving 36 persons with multiple sclerosis (MS) to examine the effect(s) of unilateral long-term (20 weeks) standardized resistance training with and without simultaneous electro-stimulation on leg muscle strength and overall functional mobility. The authors found, that long-term light to moderately intense resistance training improves muscle strength in persons with MS but simultaneous electro-stimulation does not further improve training outcome.

A clinical trial by Kesar et al. (2009) evaluated the effects of delivering FES to both ankle plantarflexors and dorsiflexors to improve gait in 13 post-stroke patients. The authors found that delivering FES to both the plantarflexor and dorsiflexor muscles can help to correct poststroke gait deficits at multiple joints (ankle and knee) during both the swing and stance phases of gait. However, this is a very small uncontrolled study.

A pilot study by Ratchford et al. (2010) evaluated the safety and preliminary efficacy of home FES cycling in 5 patients with chronic progressive multiple sclerosis (CPMS) to explore how it changes cerebrospinal fluid (CSF) cytokine levels. Outcomes were measured by: Two Minute Walk Test, Timed 25-foot Walk, Timed Up and Go Test, leg strength, Expanded Disability Status Scale (EDSS) score, and Multiple Sclerosis Functional Composite (MSFC) score. Quality-of-life was measured using the Short-Form 36 (SF-36). Cytokines and growth factors were measured in the CSF before and after FES cycling. Improvements were seen in the Two Minute Walk Test, Timed 25-foot Walk, and Timed Up and Go tests. Strength improved in muscles stimulated by the FES cycle, but not in other muscles. No change was seen in the EDSS score, but the MSFC score improved. The physical and mental health subscores and the total SF-36 score improved. The authors concluded that FES cycling was reasonably well tolerated by chronic progressive MS patients and encouraging improvements were seen in walking and quality-of-life. The study is limited by small sample. Larger studies are needed to evaluate the effects of FES for patients with MS.

The National Institute for Health and Clinical Excellence (NICE) published a guidance document in 2009 for the use of FES for foot drop of central neurological origin. NICE concluded that the evidence on safety and efficacy appears adequate to support the use of FES for foot drop in terms of improving gait, but further publication on the efficacy of FES would be useful regarding patient-reported outcomes, such as quality of life and activities of daily living.

Preliminary evidence indicates that paraplegics can benefit from functional electrical stimulation that exercises muscles without providing locomotion. In one study, electrically stimulated isometric exercise reversed bone demineralization and increased muscle strength (Belanger,
In a second study, electrically stimulated use of an exercise cycle by paraplegics restored muscle mass (Baldi, 1998). In another study, bone mineral density improved in some bones of patients with spinal cord injury (SCI) after use of the FES bicycle (Chen, 2005).

Certain studies report results with more sophisticated functional stimulators that allow some paraplegics to stand and walk. Most of the subjects enrolled in these studies succeeded in standing and walking and, using their baseline state as a control, they experienced many benefits including positive psychological changes, improved cardiovascular fitness, and increased muscle strength, muscle mass, and lower limb blood flow. However, achieving these benefits exposed the patients to significant risks (Hayes, 2003).

Despite these increased risks, the benefits of electrically stimulated ambulation do not appear to exceed those of electrically stimulated isometric or cycling exercise. While most studies involved patients with many years of muscular atrophy, Baldi et al. (1998) utilized patients with less than 4 months of atrophy. Moreover, electrically stimulated isometric exercise stimulated bone remineralization that was not observed with electrically stimulated walking (Needham-Shropshire, 1997; Belanger, 2000). The ambulation provided by functional electrical stimulation may also appear to provide an advantage over devices that only provide paraplegics with exercise but the speed and range of electrically stimulated ambulation are so limited that researchers evaluating the Parastep system concluded that it could not replace the wheelchair (Hayes, 2003). Even if the ambulation provided by devices such as the Parastep significantly improves, it will still only be usable by a subset of paraplegic patients such as those with T4-T11 spinal cord injuries (Klose, 1997). Stationary electrically stimulated exercise can be performed by a much larger group of patients including quadriplegics. To summarize, electrically stimulated ambulation cannot be considered safer or more beneficial than electrically stimulated stationary exercise unless the benefits of ambulation are shown to be superior in large-scale trials in which paraplegic patients are randomized to these two therapies. Further studies also need to be performed to confirm the benefits of electrically stimulated stationary exercise since the controlled trials conducted to date have used very small study populations and have assessed a limited set of outcome measures (Baldi, 1998; Belanger, 2000).

In a small-scale study, functional electrical stimulation significantly improved walking speed of patients with cerebral or spinal cord injuries that caused partial lower limb paralysis (Wieler, 1999). It is anticipated that large, randomized controlled trials would confirm these preliminary results and establish functional electrical stimulation as a standard therapy for patients with correctable gait disorders.

**Neuromuscular electrical stimulation (NMES) for muscle rehabilitation**

There is evidence from several randomized, controlled trials that NMES can improve wrist and finger function and prevent or correct shoulder subluxation in some patients with partial paralysis due to stroke.

Hsu et al. (2010) conducted a randomized controlled trial to investigate the effects of different doses of neuromuscular electrical stimulation (NMES) on upper-extremity function in acute stroke patients with severe motor deficit. Sixty-six acute stroke patients were equally randomized to 3 groups: high NMES, low NMES, or control. The treatment groups received NMES 5 days per week with the high-NMES group receiving 60 minutes of stimulation per day, and low-NMES group receiving 30 minutes per day for 4 weeks. The Fugl-Meyer Motor Assessment Scale, Action Research Arm Test, and Motor Activity Log were used to assess the patients at baseline, 4 and 12 weeks. Twelve subjects were lost to follow-up because of transportation difficulties (n=10) and relocation (n=2). Both NMES groups showed significant improvement on Fugl-Meyer Motor Assessment and Action Research Arm Test scales compared with the control group at week 4 and week 12. The high-NMES group showed treatment effects similar to those of the low-NMES group. The authors concluded that both higher and lower doses of NMES led to similar improvements in motor function.
In a randomized, controlled study by Ring and Rosenthal (2005), 22 patients with moderate to severe upper limb paresis 3-6 months post-onset were evaluated to assess the effects of daily neuroprosthetic (NESS Handmaster) functional electrical stimulation in sub-acute stroke. Patients were stratified into 2 groups: no active finger movement and partial active finger movements, and then randomized to control and neuroprosthesis groups. The neuroprosthesis group had significantly greater improvements in spasticity, active range of motion and scores on the functional hand tests (those with partial active motion). Of the few patients with pain and edema, there was improvement only among those in the neuroprosthesis group. There were no adverse reactions. The authors concluded that supplementing standard outpatient rehabilitation with daily home neuroprosthetic activation improve upper limb outcomes.

There are also studies that NMES can be effective when used for quadriceps strength training following ACL reconstruction or prior to total knee arthroplasty. In a small randomized controlled trial of NMES for quadriceps strength training following ACL reconstruction, the group that received NMES demonstrated moderately greater quadriceps strength at 12 weeks and moderately higher levels of knee function at both 12 and 16 weeks of rehabilitation compared to the control group (Fitzgerald, 2003). Another small study by Walls et al. (2010) evaluated the effects of preoperative NMES for 9 patients undergoing total knee arthroplasty. Five patients served as a control group. Preoperative quadriceps muscle strength increased by 28% in NMES group. Early postoperative strength loss was similar in both groups; however the NMES group had a faster recovery with greater strength over the control group at 12 weeks postoperatively.

Cauraugh and Kim (2003) examined NMES for the assistance of stroke motor recovery in a RCT of 34 stroke patients. The mixed design analyses on three categories of behavioral measures demonstrated motor improvements in the treatment group.

In 2010, Weber and colleagues reported on the use of the Bioness H200 device for use as a supplement to treatment with onabotulinumtoxinA and occupational therapy among 23 stroke patients with spasticity after stroke.[12] The primary outcome was progression in upper limb motor function, as measured by improvement in the Motor Activity Log instrument after 12 weeks of therapy. Although improvements in motor activity were seen among all patients after 6 and 12 weeks, no additional benefit was observed among patients treated with functional neuromuscular electrical stimulation versus the comparison group, potentially due to small sample size.

NMES has been used to treat a variety of other conditions including strengthening leg muscles after hip fracture and spinal cord injury, increasing wrist extension and reducing arm impairment after stroke, and providing exercise for patients with severe physical limitations due to chronic obstructive pulmonary disease or heart disease. Although RCTs that met the criteria for detailed review provided some evidence that NMES might benefit some patients with these conditions, these trials were small and did not involve sufficient follow-up to provide convincing evidence of the benefits of NMES treatment.

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated electrical stimulation for the treatment of scoliosis.

A 2008 Hayes Directory Report on Neuromuscular Electrical Stimulation for Muscle Rehabilitation states there is insufficient evidence for NMES for all other indications, including rehabilitating leg muscles after anterior cruciate ligament surgery, strengthening leg muscles after hip fracture or hip replacement surgery, strengthening muscles of the arm after spinal cord injury, improving motor function in patients with cerebral palsy, and providing exercise for patients with severe physical limitations due to chronic osteoarthritis, obstructive pulmonary disease or chronic heart failure.

Professional Societies/Organizations
The American Society of Anesthesiologists Task Force on Chronic Pain and the American Society of Regional Anesthesia and Pain Medicine practice guidelines (2011) stated that

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation: Medical Policy (Effective 02/01/2014)

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NMES may be used as part of a multimodal treatment of patients with painful peripheral nerve injuries unresponsive to other therapies.

In the evaluation of the literature regarding electrical stimulation for the treatment of spasticity in multiple sclerosis, the Multiple Sclerosis Council for Clinical Practice Guidelines (2005) stated that “surface electrical stimulation may be of benefit in reducing spasticity in persons with MS, but there is currently no evidence to support this supposition at this time.”

**Interferential therapy (IFT)**

IFT (Interferential therapy), is a treatment modality that is proposed to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. Two medium-frequency, pulsed currents are delivered via electrodes placed on the skin over the targeted area producing a low-frequency current. IFT delivers a crisscross current resulting in deeper muscle penetration. It is theorized that IFT prompts the body to secrete endorphins and other natural painkillers and stimulates parasympathetic nerve fibers to increase blood flow and reduce edema.

In 2010, Fuentes and colleagues published a systematic review and meta-analysis of studies evaluating the effectiveness of interferential stimulation for treating pain. A total of 20 studies met the following inclusion criteria: randomized controlled trial; included adults diagnosed with a painful musculoskeletal condition; compared IFS (alone or as a co-intervention) to placebo, no treatment or an alternative intervention; and assessed pain on a numeric scale. Fourteen of the trials reported data that could be included in a pooled analysis. Interferential stimulation as a stand-alone intervention was not found to be more effective than placebo or an alternative intervention.

A multi-center, randomized single-blind, controlled study by Burch et al. (2008) to investigate the benefits of the combination of interferential (IF) and patterned muscle stimulation in the treatment of osteoarthritis (OA) of the knee. The study randomized 116 patients with OA of the knee to a test or control group. The devices used to deliver the electrical stimulation were pre-programmed to deliver either IF plus patterned muscle stimulation (test group) or low-current TENS treatment (control group). Both groups were treated for 8 weeks. Subjects completed questionnaires at baseline and after 2, 4 and 8 weeks. Primary outcomes included the pain and physical function subscales of the Western Ontario MacMaster (WOMAC) OA Index and Visual Analog Scales (VAS) for pain and quality of life. The mean changes from baseline to last visit in quality of life VAS rating were similar between the two groups (18.17 vs. 18.16). Patients in the test group had a greater decrease in the overall pain VAS (27.91 vs. 23.19; P=0.29) at their last visit, but the difference between treatment groups did not achieve statistical significance. However, if only patients who completed the study (49 in test group and 50 in control group) were included for the analysis, the difference between groups in mean change from baseline increased from 4.71 to 9.40 for overall pain VAS rating and achieved statistical significance (P = 0.038). Although the study design was a randomized controlled trial of sufficient size, the study was manufacturer sponsored, with intervening treatment variables, 10% drop out rate and the treatment effect did not reach sufficient significant difference.

Jarit et al. (2003) conducted a randomized, double-blind, placebo-controlled trial of home-based, interferential therapy in 87 patients who had undergone anterior cruciate ligament (ACL) reconstruction, meniscectomy, or knee chondroplasty. Patients were divided into 3 groups based on type of knee surgery and within each group randomized into treatment and placebo group. All patients were given home IFT devices. The treatment groups received working IFT units while the placebo groups received units set to deliver no current. At baseline, there were no statistically significant differences between IFT and control groups in edema or ROM. All IFT subjects reported significantly less pain and had significantly greater range of motion at all post-operative time points. ACL and meniscectomy IFC subjects experienced significantly less edema at all time points, while chondroplasty subjects experienced significantly less edema until 4 weeks postoperatively. The authors concluded that IFT may help to reduce pain, need for pain medication and edema as well as enhance recovery of function after knee surgery. The study is
limited by subjective reporting of edema by patients, small treatment and control groups and lack of comparison to other treatment modalities. In addition, the control group was aware they were not receiving IFT thereby confounding the results.

Fourie and Bowerbank (1997) studied interferential therapy (IT) as a treatment to accelerate healing of tibial fractures in a double blind, controlled, randomized study. Forty-one men received IFT, 35 received sham, and 151 received no intervention. Outcomes were measured by the time to union or incidence of nonunion. No difference in the time for union was found in the three groups. The authors concluded that IFT did not reduce healing time for new tibial fractures or prevent nonunion.

Limited success with interferential therapy was obtained by Hurley et al. (2001) who concluded that during treatment of low back pain the interferential current must be applied to the associated spinal nerve rather than the painful area. These investigators found a statistically significant reduction in functional disability scores for the spinal nerve therapy group compared with the control group or the painful area therapy group. However, differences in pretreatment status and treatment protocols for the different patient groups in this study hamper interpretation of this finding. Moreover, no advantage was observed for spinal nerve therapy in pain scores or quality-of-life scores.

In a later study, Hurley et al. (2004) investigated the outcomes of manipulative therapy and IFT for acute low back pain. Eighty patients received manipulative therapy, 80 received IFT, and 80 received a combination of both manipulative and interferential therapies. Functional disability was assessed by the Roland Morris Disability Questionnaire. All interventions significantly reduced functional disability to the same degree at discharge, 6 months and 12 months follow-up. At discharge all interventions significantly reduced functional disability and there were no significant differences found between the groups for recurrence of back pain, work absenteeism, medication consumption, exercise participation or the use of healthcare at 12 months. The authors concluded that there was no difference between the effects of a combined manipulative therapy and interferential therapy package and either manipulative therapy or interferential therapy alone.

A 2008 (2012 Updated) Hayes Directory Report on Interferential Therapy for Pain and Bone Fractures states there is a lack of evidence that interferential therapy is effective for pain relief and tissue healing.

In 2005, the California Technology Assessment Forum (CTAF) concluded that interferential therapy has not been shown to be as beneficial as the alternatives for the treatment of musculoskeletal pain. Validated treatments for musculoskeletal pain include medication as necessary, such as acetaminophen, nonsteroidal anti-inflammatory agents, muscle relaxants or opioids; discourage bed rest, consider spinal manipulation for pain relief and refer for exercise therapy.

The body of evidence on interferential therapy (IFT) includes a number of randomized controlled trials (RCTs) and a meta-analysis of RCTs. Several studies reported no significant difference between IFT treatment groups compared to placebo or other co-interventions. Studies which have reported some benefit of IFT treatment for pain have been limited by small sample size, limited follow-up, and lack of placebo control groups. Overall, the evidence suggests that IFS is not efficacious for improving pain, function and/or range of motion for patients with musculoskeletal conditions;

Professional Societies/Organizations:
The Work Loss Data Institute (2009) stated that “there is no quality evidence of effectiveness except in conjunction with recommended treatments, including return to work, exercise and medications” and the evidence of improvement was limited. The reported results from trials were negative or non-interpretable and study design and methodology were poor. There was a lack of
standardized protocol for IFT, and the therapies varied in electrode-placement technique, frequency of stimulation, pulse duration, and treatment time.

Clinical practice guidelines from the American College of Physicians and the American Pain Society published in 2007 concluded that there was insufficient evidence to recommend interferential stimulation for the treatment of low back pain.

Pulsed Electrical Stimulation (PES)
The BioniCare Knee System (formerly Bio-1000 system), is a noninvasive, low-amplitude, pulsed electrical stimulation (PES) device designed to reduce pain and improve function in patients with osteoarthritis (OA) of the knee. The device consists of a signal generator, signal applicator, and electrodes encased in either a supportive knee brace or a soft wrap. PES is delivered to the knee and the brace is worn by the patient for ≥ 6 hours per day during waking hours; the soft wrap is used overnight while sleeping. During an in-office consultation, the healthcare professional instructs the patient in proper use of the device. PES is intended for patients with knee pain due to OA who do not respond well to nonsteroidal, anti-inflammatory drug treatment or who are not appropriate candidates for, or do not wish to undergo, total knee arthroplasty (TKA). Hayes Technology Brief (2011).

A double-blind, randomized, placebo-controlled trial by Fary et al. (2011) evaluated the effectiveness of pulsed electrical stimulation in the symptomatic management of osteoarthritis (OA) of the knee. Thirty-four patients were randomized to PES and 36 to placebo. Primary outcomes measured pain by visual analog scale (VAS). Other measures included Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores for pain, function, and joint stiffness, Short-Form 36 health survey and perceived effect on quality of life and physical activity. Over 26 weeks, both groups showed improvement in pain scores. There were no differences between groups for changes in WOMAC pain, function, and stiffness scores, SF-36 physical and mental component summary scores, patient's global assessment of disease activity or activity measures. Fifty-six percent of the PES-treated group achieved a clinically relevant 20-mm improvement in VAS pain score at 26 weeks compared with 44% of controls. The authors concluded that PES was no more effective than placebo in managing osteoarthritis of the knee.

A randomized controlled trial conducted and supported by the manufacturer of the BIO-1000 System evaluated the analgesic potential and functional improvement following the use of PES in patients (n=78) with osteoarthritis (OA) of the knee (Zizic, 1995). Patients were randomized to receive an active device or a placebo device, both of which were used daily for 4 weeks. Three primary efficacy variables (patient pain, patient function, and physician global evaluation of patient condition) and 6 secondary variables (duration of morning stiffness, range of motion, knee tenderness, joint swelling, joint circumference, and walking time) were assessed. Patients treated with the active device demonstrated significantly better improvement than the placebo group for all primary efficacy variables in comparison of mean change from baseline to the end of treatment. There was 50% improvement in all three primary efficacy variables in 24% of the active device group versus 6% of the placebo group. No statistically significant differences were observed for tenderness, swelling, or walking time. This study is limited by short follow-up, lack of power analysis, 9% of patients were not evaluable at follow-up, and manufacturer sponsor.

Farr et al. (2006) reported on a prospective, cohort study examining the use of PES for the treatment of osteoarthritis of the knee in 288 patients. The device was used for 16 to 600 days with a mean of 889 hours. Improvement in all efficacy variables was reported. A dose-response relationship between the effect and hours of usage was observed as cumulative time increased to more than 750 hours. Improvements in the patient's or physician's global evaluation of the patient's condition occurred in 59% of patients who used PES less than 750 hours and in 73% of patient's who used it more than 750 hours. The lack of a control group weakens the evidence of this study.

Mont et al. (2006) examined the use of PES to defer total knee arthroplasty (TKA) for patients...
Peripheral Subcutaneous Field Stimulation (PSFS) or Peripheral Nerve Field Stimulation (PNFS)
Subcutaneous stimulation (peripheral nerve field stimulation/PNFS) is a novel neuromodulation modality that has increased in its utilization during the past decade. In this particular treatment, an electrical current is transmitted via an electrode that has been implanted around the selected peripheral nerve. This electrical current purports to block or disrupt the normal transmission of pain signals. The electrodes are connected by a wire to the peripherally implanted neurostimulator (also known as an implantable subcutaneous target stimulator). An external generator (similar to a remote control device) controls the degree of stimulation the patient receives.

Yakovlev et al. (2011) evaluated peripheral nerve field stimulation (PNFS) as an alternative treatment option for patients with postlaminectomy syndrome (PLS) when conventional treatments did not provide adequate relief of intractable low back pain. Eighteen patients underwent an uneventful PNFS trial with percutaneous placement of four temporary quadripolar leads. The leads were placed subcutaneously over the lumbar or thoraco-lumbar area. The temporary leads were removed when patients experienced excellent pain relief over the next two days. The patients were then implanted with permanent leads. All patients reported sustained pain relief 12 months after implantation. The authors concluded that PNFS may be more effective in treating intractable low back pain than spinal cord stimulation in patients with PLS after multilevel spinal surgeries. The lack of a control group limits the validity of the conclusions of this study.

Verrills et al. (2011) evaluated the clinical outcomes of 100 consecutive patients receiving peripheral nerve field stimulation (PNFS) for chronic pain in a prospective, observational study. The patients received PNFS for the treatment of chronic craniofacial, thorax, lumbosacral, abdominal, pelvic, and groin pain conditions. Overall, 72% of patients reduced their analgesic use following PNFS. Patients receiving a lumbosacral PNFS for chronic low back pain reported a significant reduction in disability following treatment, as determined by the Oswestry Disability Index. No long-term complications were reported. The authors concluded that PNFS can be a safe and effective treatment option for intractable chronic pain conditions. This study was not randomized or case controlled.

Six patients with failed back surgery syndrome who had failed conventional therapies were implanted in the subcutaneous tissues of the low back region with neurostimulation leads. Leads were placed superficially in the region of maximum pain, as identified by each individual patient. The use of peripheral nerve field stimulation (PNFS) enabled patients to decrease their pain medication and increase their level of activity. The patients all reported reduction in pain as measured by visual analog scale scores and an improved quality of life. The authors concluded that PNFS is a safe and effective alternative treatment for patients with chronic low back pain, and should be considered in this population (Paicius, 2007). This study is limited by a small study population.

Evidence on PSFS is limited, consisting of small uncontrolled and case studies. Prospective controlled trials are needed to evaluate the efficacy of this treatment for chronic pain.

**Interferential stimulators** are regulated by the FDA as Class II devices under product codes LIH and IPF. More than 50 instruments have received 510(k) approval.

A complete list of devices for IF is too extensive for inclusion in this report. The FDA-approved list includes:

- Endomed 433, 582 and 982 Interferential Stimulators (Enraf Nonius, Delft, The Netherlands)
- Galva Electrotherapy System (Zimmer Elektromedizin, Neu-Ulm, Germany)
- Omega Inter 4150 (Medical Industries Australia Pty. Ltd., Sydney, Australia)
- INF Plus™ (Biomedical Life Systems Inc, Vista, CA)
- Stimtech® IF4 (Stitch, Amherst, NH)
- RSJ, RS JC (RS Medical, Vancouver, WA)
- IF 8000 (Biomotion, Madison, AL)
- RS-4i™ (RS Medical, Vancouver, WA)


The **WalkAide** is a product of Myo-Orthotics Technology, a term coined by the manufacturer, Innovative Neurotronics (Austin, TX). According to the manufacturer, it represents the convergence of orthotic technology (which braces a limb) and ES (which restores specific muscle function). The WalkAide device is intended to counteract foot drop by producing dorsiflexion of the ankle during the swing phase of the gait. The device attaches to the leg, just below the knee, near the head of the fibula. During a gait cycle, the WalkAide stimulates the common peroneal nerve, which innervates the tibialis anterior and other muscles that produce dorsiflexion of the ankle. The WalkAide is designed to offer persons with foot drop increased mobility, functionality and independence. It was cleared by the FDA through the 510(k) process. However, there is currently insufficient evidence to support its use for foot drop and other indications. Prospective clinical studies of the WalkAide device are necessary to evaluate whether it improves function and reduces disability compared to standard bracing in persons with foot drop.

The **NESS L300** received 510(k) marketing clearance on July 7, 2006. The NESS L300 is intended to provide ankle dorsiflexion in individuals with drop foot following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot; thus, it may improve the individual's gait. The NESS L300 may also facilitate muscle re-education, prevent/retard disused atrophy,

The ODFS Dropped Foot Stimulator (Odstock) received FDA approval on July 15, 2005. The ODFS is intended to provide ankle dorsiflexion in individuals with dropped foot following an upper motor neuron injury. During the swing phase of gait, the ODFS electrically stimulates muscles in the leg and ankle of partially paralyzed individuals to provide flexion of the foot and may thus improve the individual's gait. Additional information (product code GZI and IPF) is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K050991.pdf. Accessed October 15, 2013.


The NESS Neuromuscular Electrical Stimulation System or Handmaster was approved through 510(K) on September 11, 2002. The most recent approval is under the name Handmaster in 2003. The NESS System is intended to be used for the following indications: maintenance or increase of range of motion, reduction of muscle spasm, prevention or retardation of disuse atrophy, muscle reeducation, and increasing local blood circulation. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K031900.pdf. Accessed October 15, 2013.


The RT300 FES cycle ergometer was approved as a powered muscle stimulator 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 June 27, 2005. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K090750.pdf. Accessed October 15, 2013.

The BioniCare BIO-1000 System (product code NYN), a pulsed electrical stimulation system, is classified as a stimulator, electrical, transcutaneous for arthritis device by the FDA and is designed to help reduce pain and improve function in osteoarthritis of the knee. It received 510(k) approval on June 6, 2003. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/K030332.pdf. Accessed October 15, 2013.

Peripheral Subcutaneous Field Stimulation (PSFS) or Peripheral Nerve Field Stimulation (PNFS) using a fully implantable system is not currently approved by the FDA. See the following Web site for more information: http://www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1306157336003&lang=en_US. Accessed October 15, 2013.

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare covers electrical nerve stimulators when criteria are met. Refer to the National Coverage Determinations (NCDs) for Electrical Nerve Stimulators (160.7), Transcutaneous Electrical Nerve Stimulators (TENS) (280.13), Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2), Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13), Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2) and Phrenic Nerve Stimulator (160.19).

Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Transcutaneous Electrical Nerve Stimulators (TENS).

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation: Medical Policy (Effective 02/01/2014)
Medicare does not have a National Coverage Determination for Spinal Cord Stimulators. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for **Spinal Cord Stimulation (Dorsal Column Stimulation)**.

Medicare covers neuromuscular electrical stimulation (NMES) and functional electrical stimulation (FES) when criteria are met. Refer to the NCD for **Neuromuscular Electrical Stimulator (NMES)** (160.12). Local Coverage Determinations (LCDs) do not exist at this time.

Medicare does not have a National Coverage Determination (NCD) for pulsed electrical stimulation (PES). Local Coverage Determinations (LCDs) do not exist at this time.

Medicare does not have a National Coverage Determination (NCD) for Interferential Therapy. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for **Medicine: Physical Therapy -Outpatient**, **Outpatient Physical and Occupational Therapy Services** and **Outpatient Physical Therapy**

(Accessed October 23, 2013)

### APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural -</td>
</tr>
<tr>
<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
</tr>
<tr>
<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>0282T</td>
<td>Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar; for trial, including removal at the conclusion of trial period</td>
</tr>
<tr>
<td>0283T</td>
<td>permanent, with implantation of a pulse generator</td>
</tr>
<tr>
<td>0284T</td>
<td>Revision or removal of pulse generator or electrodes, including imaging guidance, when performed, including addition of new electrodes, when performed</td>
</tr>
<tr>
<td>0285T</td>
<td>Electronic analysis of implanted peripheral subcutaneous field stimulation pulse generator, with reprogramming when performed</td>
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*CPT® is a registered trademark of the American Medical Association.*

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0744</td>
<td>Neuromuscular stimulator for scoliosis</td>
</tr>
<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
</tr>
<tr>
<td>E0762</td>
<td>Transcutaneous electrical joint stimulation device system, includes all accessories</td>
</tr>
<tr>
<td>E0764</td>
<td>Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program</td>
</tr>
</tbody>
</table>

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Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation: Medical Policy (Effective 02/01/2014)

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<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0770</td>
<td>Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified</td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
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<tr>
<td>L8684</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
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<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
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<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
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<tr>
<td>L8688</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
</tr>
<tr>
<td>S8130</td>
<td>Interferential current stimulator, 2 channel</td>
</tr>
<tr>
<td>S8131</td>
<td>Interferential current stimulator, 4 channel</td>
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</tbody>
</table>

**Coding Clarification**

Transcutaneous electrical joint stimulation devices (E0762) are noninvasive devices that deliver low-amplitude pulsed electrical stimulation.

**REFERENCES**

Abejon D, Krames ES. Peripheral nerve stimulation or is it peripheral subcutaneous filed stimulation; what is in a moniker? *Neuromodulation* 2009; 12:1–3.


**POLICY HISTORY/REVISION INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tr>
<td>02/01/2014</td>
<td>• Updated description of services to reflect most current clinical evidence, FDA information and references</td>
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<tr>
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<td>• Revised coverage rationale; added language to indicate interferential therapy (IFT) is unproven for the treatment of musculoskeletal disorders or injuries, or stimulating healing of nonsurgical soft tissue injuries</td>
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<tr>
<td></td>
<td>• Updated list of applicable CPT codes to reflect annual code edits; added L8679</td>
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<tr>
<td></td>
<td>• Archived previous policy version 2013T0126P</td>
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