ELECTRICAL STIMULATION FOR THE TREATMENT OF PAIN AND MUSCLE REHABILITATION

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

When used for walking, functional electrical stimulation (FES), a form of neuromuscular electrical stimulation (NMES), is proven and medically necessary when used as one component of a comprehensive rehabilitation program 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 SCI and restorative surgery of at least 6-months;
• No hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis

Further studies are needed to confirm that FES promotes bone remineralization and prevents or reverses muscle atrophy. Only a few studies have looked at FES as a modality of treatment of MS, and the results are limited and conflicting regarding whether FES improves treatment outcomes in MS when offered in addition to other rehabilitative treatment modalities. There is insufficient evidence in the peer reviewed literature that use of FES 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.

Neuromuscular electrical stimulation (NMES) is proven and medically necessary for treating the following indications:
• Disuse muscle atrophy if:
  o The nerve supply to the muscle is intact; and
  o The disuse muscle atrophy is not of neurological origin but originates from conditions such as casting, splinting or contractures.
• 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 and not medically necessary for treating ANY other indication not listed above as proven and medically necessary.

Interferential therapy (IFT) is unproven and not medically necessary for treating the following indications:
• For the treatment of musculoskeletal disorders or injuries
• For stimulating healing of nonsurgical soft tissue injuries
• To facilitate the healing of bone fractures

Pulsed electrical stimulation (PES) is unproven and not medically necessary for treating osteoarthritis.

Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS) is unproven and not medically necessary for treating 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.
Microcurrent electrical nerve stimulation (MENS) therapy is unproven and not medically necessary. There is insufficient evidence to conclude that microcurrent electrical nerve stimulation is safe and effective. Robust clinical trials are needed to evaluate this therapy in comparison to other types of treatment.

Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary. There is limited evidence in the peer reviewed literature to support that DRG stimulation will improve health outcomes in patients with pain. Randomized controlled trials assessing larger patient groups and long-term follow up are needed to further clarify its role.

A description of dorsal root ganglion neurostimulation devices is located in the FDA section. Click here for more information.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<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>
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**HCPCS Code**

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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<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>
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<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>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<td>L8680</td>
<td>Implantable neurostimulator electrode, each</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>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
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<td>L8686</td>
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<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension</td>
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<tr>
<td>S8130</td>
<td>Interferential current stimulator, 2 channel</td>
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<tr>
<td>S8131</td>
<td>Interferential current stimulator, 4 channel</td>
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**Coding Clarification:** Transcutaneous electrical joint stimulation devices (E0762) are noninvasive devices that deliver low-amplitude pulsed electrical stimulation.
DESCRIPTION OF SERVICES

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, implanted transcutaneously, or surface.

**Functional Electrical Stimulation (FES)**

Functional electrical stimulation (FES) is the direct application of electric current to intact nerve fibers in a coordinated fashion to cause involuntary but purposeful contraction. FES bypasses the central nervous system and targets motor neurons innervating either skeletal muscle or other organ systems. Electrodes may be on the surface of the skin or may be surgically implanted along with a stimulator. FES is categorized as therapeutic and functional. Therapeutic FES enables typically resistive exercise, with the goal of preventing muscular atrophy and promoting cardiovascular conditioning. Functional FES enables or enhances standing, ambulation, grasping, pinching, reaching, respiration, bowel or bladder voiding, or ejaculation. The two goals of FES are mutually supportive. FES is a task-specific variant of neuromuscular electrical stimulation (NMES) (Hayes, 2015).

**Neuromuscular Electrical Stimulation (NMES)**

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).

**Interferential Therapy (IFT)**

Interferential therapy (IFT) is the superficial application of a medium-frequency alternating current modulated to produce low frequencies up to 150 Hz. It is thought to increase blood flow to tissues and provide pain relief and is considered more comfortable for patients than transcutaneous electrical nerve stimulation (Chou, et al. 2007).

**Pulsed Electrical Stimulation (PES)**

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)**

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 or does not fit exactly within the area served by any one or two peripheral nerves. Different from spinal cord stimulation (SCS) or peripheral nerve stimulation (PNS). The electrode arrays are implanted within the subcutaneous tissue of the painful area, not on or around identified neural structures, but most probably in or around cutaneous nerve endings of the intended nerve to stimulate (Abejon and Krames, 2009).

**Microcurrent Electrical Nerve Stimulation Therapy (MENS)**

Microcurrent electrical neuromuscular stimulation (MENS) is intended for pain relief and to facilitate wound healing, delivering current in the microampere range. One micro amp (μA) equals 1/1000th of a milliamp (mA). By comparison, TENS therapy delivers currents in the milliamp range causing muscle contraction, pulsing and tingling sensations. The microcurrent stimulus is subsensorial so users cannot not detect it. Although microcurrent devices are approved in the category of TENS for regulatory convenience, in practical use they are in no way similar and cannot be compared to TENS in their effect (Curtis, et al. 2010; Zuim, et al. 2006). MENS is also referred to as microelectrical therapy (MET) or microelectrical neuro-stimulation. Examples of MENS devices currently in use include, but are not limited to, Algonix®, Alpha-Stim®100, Microcurrent, and Micro Plus™.

**Dorsal Root Ganglion Stimulation**

Dorsal root ganglion (DRG) stimulation therapy may be prescribed for pain that is limited to a specific area of the body that starts in a lower part of the body (e.g., foot, knee, hip and groin) following an injury or surgical procedure and grows worse over time. DRGs are spinal structures densely populated with sensory nerves that transmit information to the brain via the spinal column. Through the use of a neurostimulator system such as AXIUM™, physicians are able to directly treat targeted areas of the body where pain occurs. (St. Jude Medical, 2017)
**Functional Electrical Stimulation (FES)**

FES has been proposed for improving ambulation in patients with gait disorders such as drop foot, hemiplegia due to stroke, cerebral injury, or incomplete spinal cord injury. Randomized controlled trials and case series have primarily included small patient populations with short-term follow-ups.

Hayes performed evidence review from 8 studies that evaluated FES for treatment of foot drop in patients with MS. There was no available evidence regarding implantable FES devices and the majority of the studies used the Odstock ODFS devices, and the others used the WalkAide System. Overall, low-quality body of evidence derived from the studies suggests that during well-controlled walking tests, FES can increase walking speed, improve gait quality, reduce falls, and improve activities of daily living (ADL) and quality of life (QOL) in patients with foot drop due to MS. However, while some studies reported significant increases in walking speed with FES, ranging from 7% to 27% compared with baseline, it is unclear whether these improvements are clinically meaningful in a real-life setting. There was no evidence suggesting that the use of the FES device helped MS patients reach normal walking speed. In addition, 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, or perform side steps; or whether its use improved confidence while performing these various activities.

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 (2011, updated 2016).

Chiu and Ada (2014) conducted a systematic review to determine the effectiveness of FES versus activity training alone in children with cerebral palsy (CP). Five randomized controlled trials met inclusion criteria. The experimental group had to receive FES while performing an activity such as walking. The studies used outcome measures of activity that best reflected the activity used in the study. When continuous data (e.g., walking speed) were not available, ordinal data (e.g., Gross Motor Function Measurement) were used. A statistically significant between-group difference in activity in the FES groups was reported for the 3 studies that compared FES with no FES. Improvements were seen immediately after the intervention period, but long-term follow-up was not reported. The 2 studies investigating the effects of FES vs. activity training reported no significant differences between the groups. The results reported that FES is better than no FES but that FES is not more effective than activity training. The authors stated that they may be fairly confident that FES is effective given that all 3 trials reported between-group differences in favor of FES, but with no meta-analysis providing an effect size, it is not possible to judge the clinical significance of the benefit.

Limitations of the studies included the heterogeneous patient populations and the variations in the frequency, intensity and duration of the interventions.

A 2016 randomized control trial by El-Shamy and Abdelaai assessed the effects of the WalkAide FES on gait pattern and energy expenditure in children with hemiplegic CP. Seventeen children were assigned to the study group, whose members received FES (pulse width, 300 μs; frequency, 33 Hz, 2 hours/d, 3 days/week for 3 consecutive months). Seventeen other children were assigned to the control group, whose members participated in a conventional physical therapy exercise program for 3 consecutive months. Baseline and posttreatment assessments were performed using the GAITRite system to evaluate gait parameters and using an open-circuit indirect calorimeter to evaluate energy expenditure. Children in the study group showed a significant improvement when compared with those in the control group ($P < 0.005$). The gait parameters (stride length, cadence, speed, cycle time, and stance phase percentage) after treatment were (0.74 m,119 steps/min, 0.75 m/s, 0.65 s, 55.9%) and (0.5 m,125 steps/min, 0.6 m/s, 0.49 s, 50.4%) for the study group and control group, respectively. The mean energy expenditures after treatment were $8.18 \pm 0.88$ and $9.16 \pm 0.65$ mL/kg per minute for the study and control groups, respectively. The authors concluded that WalkAide functional electrical stimulation may be a useful tool for improving gait pattern and energy expenditure in children with hemiplegic cerebral palsy. The study was limited to a small sample size.

A randomized control trial by Pool et al. evaluated whether neuromuscular electrical stimulation (NMES) applied to the ankle dorsiflexors during gait improves muscle volume and strength in children with unilateral spastic CP. The study involved 32 children (mean age of 10.5 years) and a Gross Motor Function Classification System of I or II. Participants were randomly assigned to either the 8-week daily NMES treatment group or control group (usual or conventional treatments). Outcomes at week 8 (post-NMES) and week 14 (carryover) included magnetic resonance imaging (MRI) for muscle volumes (tibialis anterior, anterior compartment, and gastrocnemius), strength (hand-held dynamometry for isometric dorsiflexion strength and heel raises for functional strength), and clinical measures for lower limb selective motor control. At week 8, the treatment group demonstrated significantly ($p<0.05$) increased...
In 2014, Pool and colleagues also studied children with unilateral spastic CP to determine the effects of FES on the main impairments affecting gait. A 20-week, multiple single-subject A-B-A design included a 6-week pre-FES phase, an 8-week FES phase, and a 6-week post-FES phase. Twelve children (aged 5 to 16 years) wore an FES device (the Walk Aide) daily for 8 weeks. Weekly measures included ankle range of motion (ROM), selective motor control, dorsiflexion and plantar flexion strength, gastrocnemius spasticity, single-limb balance, Observational Gait Scale (OGS) score, and self-reported toe drag and falls in the community. Compared with the pre-FES phase, the FES phase showed significant improvements in ankle ROM, selective motor control and strength, and reductions in spasticity, toe drag, and falls, but no change in OGS score. These improvements were maintained during the post-FES phase. The authors concluded that intermittent, short-term use of FES is potentially effective for reducing impairments affecting gait in children with unilateral spastic CP. The study was limited to a small sample size.

Broekmans et al. (2011) conducted a randomized controlled study involving 36 persons with 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: 2-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. QOL 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 2-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 CPMS patients and encouraging improvements were seen in walking and QOL. 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 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 QOL and activities of daily living (2009, updated 2012).

Preliminary evidence indicates that paraplegics can benefit from FES that exercises muscles without providing locomotion. In one 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). 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. 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, 1997B). 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 2 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.
Neuromuscular Electrical Stimulation (NMES) for Muscle Rehabilitation

Although the evidence is limited, NMES for the treatment of disuse atrophy in patients where the nerve supply to the muscle is intact appears to be considered standard of care. There is some evidence that the use of NMES may be an effective rehabilitative regimen to prevent muscle atrophy associated with prolonged knee immobilization following ligament reconstruction surgery or injury; however, controlled clinical trials are necessary to determine if the addition of NMES to the rehabilitation program will improve health outcomes.

De Oliveira Melo et al. (2013) conducted a systematic review to identify the evidence for NMES for strengthening quadriceps muscles in elderly patients with knee osteoarthritis (OA). Six randomized controlled trials met inclusion criteria. Four studies included ≤ 50 patients. Study designs and outcome measures were heterogeneous and comparators varied. NMES parameters were poorly reported. The trials scored extremely low on the allocation concealment and blinding items. In most of the trials, the randomization methods were not described. Due to the poor methodology of the studies and poor description of the strength measurement methods, no or insufficient evidence was found to support NMES alone or combined with other modalities for the treatment of elderly patients with OA. Due to the study limitations, no meta-analysis was performed.

Lin et al. (2011) completed a randomized, single-blinded, controlled trial study to investigate the long-term efficacy of NMES in enhancing motor recovery in the upper extremities of stroke patients. A total of 46 patients with stroke were assigned to a NMES group or a control group. Patients in the NMES group received the treatment for 30 min, 5 days a week for 3 weeks. Measurements were recorded before treatment, at the 2nd and 3rd week of treatment and 1, 3 and 6 months after treatment ended. The Modified Ashworth Scale for spasticity, the upper extremity section of the Fugl-Meyer Motor Assessment (FMA), and the Modified Barthel Index were used to assess the results. Significant improvements were found in both groups in terms of Fugl-Meyer motor assessment, and Modified Ashworth Scale scores after the 3rd week of treatment. The significant improvements persisted 1 month after treatment had been discontinued. At 3 and 6 months post-treatment, the average scores in the NMES group were significantly better than those in the control group. The authors concluded that 3 weeks of NMES to the affected upper extremity of patients with stroke improves motor recovery. One limitation of this study was the absence of a sham stimulation group. Future studies, using similar stimulation protocols with a larger sample, are needed to gain further insight into the potential to induce functionally beneficial neuroplasticity in stroke patients.

In a randomized controlled study by Shen et al. (2015), contralaterally controlled functional electrical stimulation (CCFES) was compared to NMES as an innovative method to improve upper extremity functions after stroke. Sixty-six patients were also treated with conventional medical treatment and rehabilitation training, and were equally randomized into 2 groups. The treatments were administered in 20 minute sessions, 5 times per week for 3 weeks. Tools to assess results included the FMA, motricity index (MI), the Hong Kong version of functional test for the hemiplegic upper extremity (FTHUE-HK) and active range of motion (AROM) of wrist extension. Patient status was measured before and after 3 weeks of treatment. Both groups showed significant improvements in all the measurements after treatment. Patients in CCFES group showed significantly higher upper extremity FMA, FTHUE-HK scores and AROM of wrist extension than those in NMES group. The authors concluded that compared with the conventional NMES, CCFES provides better recovery of upper extremity function in patients with stroke.

Hsu et al. (2010) conducted a randomized controlled trial to investigate the effects of different doses of 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 FMA, Action Research Arm Test, and Motor Activity Log (MAL) were used to assess the patients at baseline, 4 and 12 weeks. Twelve subjects were lost to follow-up. Both NMES groups showed significant improvement on FMA and Action Research Arm Test scales compared with the control group at weeks 4 and 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 prospective, longitudinal randomized controlled trial, 66 patients, aged 50 to 85 years and planning a primary unilateral total knee arthroplasty (TKA), were randomly assigned to receive either standard rehabilitation (control) or standard rehabilitation plus NMES applied to the quadriceps muscle (initiated 48 hours after surgery). The NMES was applied twice per day at the maximum tolerable intensity for 15 contractions. Data for muscle strength, functional performance, and self-report measures were obtained before surgery and 3.5, 6.5, 13, 26, and 52 weeks after TKA.
At 3.5 weeks after TKA, significant improvements with NMES were found for quadriceps and hamstring muscle strength, functional performance, and knee extension active range of motion (AROM). At 52 weeks, the differences between groups were attenuated, but improvements with NMES were still significant for quadriceps and hamstring muscle strength, functional performance, and some self-report measures. The authors concluded that the early addition of NMES effectively attenuated loss of quadriceps muscle strength and improved functional performance following TKA. The effects were most pronounced and clinically meaningful within the first month after surgery, but persisted through 1 year after surgery. Further research focused on early intervention after TKA is warranted to continue to optimize patient outcomes (Stevens-Lapsley et al., 2012).

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 neuromuscular (NESS Handmaster) FES 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 neuromuscle groups. The neuromuscle group had significantly greater improvements in spasticity, AROM 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 neuromuscle group. There were no adverse reactions. The authors concluded that supplementing standard outpatient rehabilitation with daily home neuromuscle activation improves upper limb outcomes.

There are also studies that NMES can be effective when used for quadriceps strength training following anterior cruciate ligament (ACL) reconstruction or prior to total knee arthroplasty (TKA). 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 TKA. 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.

In a 2008 systematic review of ACL reconstruction rehabilitation, Wright et al. reported that 14 randomized controlled trials had evaluated postoperative NMES following ACL reconstruction. Study limitations included the following: poor study design; heterogeneous patient populations; and lack of independent observers. The authors noted that it was difficult to make generalized conclusions regarding NMES for this indication.

In 2010, Weber et al. conducted a randomized controlled trial to assess whether OnabotulinumtoxinA injections and occupational therapy with or without FES improved upper limb motor function in 23 stroke patients with chronic spastic hemiparesis. 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 NMES 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.

**Professional Societies**

**American Heart Association/American Stroke Association (AHA/ASA)**

In its Guidelines for Adult Stroke Rehabilitation and Recovery, the AHA/ASA state that NMES combined with therapy may improve spasticity, but there is insufficient evidence that the addition of NMES improves functional gait or hand use. The AHA/ASA guidelines are endorsed by the American Academy of Physical Medicine and Rehabilitation and the American Society of Neurorehabilitation (Winstein et al., 2016).

**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. The body of evidence on 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 IFT is not found to be more effective than alternative interventions for improving pain, function and/or range of motion for patients with musculoskeletal conditions.

**Musculoskeletal Pain**

In 2010, Fuentes and colleagues published a systematic review and meta-analysis of studies evaluating the effectiveness of interferential stimulation (IFS) 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. IFS as a stand-alone intervention was not found to be more effective than placebo or an alternative intervention.

**Osteoarthritis**

Gundog et al. (2012) conducted a randomized controlled trial to compare the effectiveness of interferential current therapy (IFT) to sham IFC for the treatment of osteoarthritis (OA). Sixty patients were allocated to 3 active IFC groups (40, 100, and 180 Hz), and one sham IFC group. Treatments were administered for 20 minutes, 5 times per week, for 3 consecutive weeks. Each patient was assessed at the end of the treatments and at the first month using the following measurements: Visual Analog Scale (VAS) (pain at rest and with movement), physician and patient judgments regarding treatment effectiveness, 15-meter walking time (in minutes), range of motion (ROM), the Western Ontario and McMaster University Osteoarthritis Index (WOMAC), and paracetamol intake. Although there were significant improvements in most variables measured in all groups, the improvements were greater in active IFC groups than in the sham group. The improvement in WOMAC stiffness was observed only in active IFC treatment groups. No significant difference between different amplitude-modulated frequencies of IFC treatments was observed. The authors concluded that the study demonstrated the superiority of the IFC with some advantages on pain and disability outcomes when compared with sham IFC for the management of knee OA. Limitations of the study included small patient population, difficulty finding patients who met inclusion criteria, and short-term follow-up.

A multi-center, randomized single-blind, controlled study by Burch et al. (2008) investigated the benefits of combined interferential (IF) and patterned muscle stimulation in the treatment of OA of the knee. The study randomized 116 patients to a test or control group. The test group received 15 minutes of IF stimulation followed by 20 minutes of patterned muscle stimulation. The control group received 35 minutes of low-current transcutaneous electrical nerve stimulation (TENS). 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 WOMAC OA Index and VAS for pain and QOL. Compared to the control group, the test group showed reduced pain and increased function. The test group showed a greater decrease in the WOMAC pain subscale (P=0.002), function subscale (P=0.003) and stiffness subscale (P=0.004). More than 70% of the test group, compared to less than 50% of the control group, had at least a 20% reduction in the WOMAC pain subscale. When analyzing only patients who completed the study (N=49 in test group, N=50 in control group), the test group had a nominally significant greater decrease in overall pain VAS. No significant differences were observed between groups related to incidence of adverse events. The authors concluded that in patients with OA of the knee, home-based patterned stimulation appears to be a promising therapy for relieving pain, decreasing stiffness, and increasing function. Study limitations included manufacturer sponsoring, 10% drop out rate and the treatment effect did not reflect a sufficient significant difference.

**Anterior Cruciate Ligament / Meniscectomy / Knee Chondroplasty**

Jarit et al. (2003) conducted a randomized, double-blind, placebo-controlled trial of home-based, interferential therapy (IFT) 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 ROM at all post-operative time points. ACL and meniscectomy IFT 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.

**Tibial Fractures**

Fourie and Bowerbank (1997) studied interferential current (IFIC) as a treatment to accelerate healing of tibial fractures in a double blind, controlled, randomized study. Forty-one men received IFC, 35 received sham, and 151
received no intervention. Outcomes were measured by the time to union or incidence of nonunion. IFCs were applied to the experimental group via suction electrodes for 30 minutes per day for 10 days. The placebo group had only suction electrodes applied producing a rhythmic massage effect. The control group received no intervention. The data analysis reflected no difference in the time for union in the 3 groups. The authors concluded that IFC did not reduce healing time for new tibial fractures or prevent nonunion, and that further investigation was recommended.

**Low Back Pain**

To assess the influence of Transcutaneous Electrical Nerve Stimulation (TENS) and interferential current (IFC) on pain relief and to compare the analgesic efficacy of the 2 modalities, Grabianska et al. (2015) studied 60 patients with low back pain (LBP). The participants were equally and randomly divided into 2 groups. Depending on the groups, patients were given a series of ten 20-minute sessions over a 2 week period using either IFC or TENS currents. In all patients,VAS and Laitinen modified scale were taken before and after treatment. At the end of the 2 weeks, there was improvement in nearly all components of the VAS and Laitinen scale for both groups. There was no statistically significant difference between the groups in reducing the intensity and other aspects of pain (e.g., frequency, pain medication and activity limitation). The authors concluded that both IFC and TENS therapy are effective for pain relief in patients with LBP, as their study results demonstrated equal analgesic efficacy of both therapy modalities.

Hurley et al. (2001) conducted a single-blind, randomized, controlled trial on 60 subjects with low back pain (LBP), evaluating whether the IFC applied to the associated spinal nerve is more efficacious than placing the current over 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, no advantage was observed for the spinal nerve therapy group in pain or QOL scores. The authors’ findings showed that IFT electrode placement technique affects LBP-specific functional disability, providing preliminary implications for future clinical studies.

In a later study, Hurley et al. (2004) investigated the outcomes of manipulative therapy and interferential therapy (IFT) used as sole modalities or in combination for treatment of acute LBP. Eighty patients received manipulative therapy, 80 received IFT, and 80 received a combination of both manipulative and IFT. The primary outcome was a change in functional disability on the Roland Morris Disability Questionnaire. Follow-up questionnaires were posted at discharge and at 6 and 12 months. At discharge, all interventions significantly reduced functional disability. At 12 months, 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. The authors concluded that there was no difference between the effects of a combined manipulative therapy and IFT package and either of the therapy modalities alone.

In 2016, the Agency for Healthcare Research and Quality (AHRQ) issued a comparative effectiveness review on the benefits and harms of pharmacological and nonpharmacological noninvasive treatments for LBP. Of the 2,545 citations identified at the title and abstract level, a total of 156 publications were included. Relative to interferential therapy (IFT), the authors concluded that the evidence was insufficient from 4 trials to determine effects of IFT versus other interventions, or IFT plus another intervention versus the other intervention alone, due to methodological limitations and imprecision (Chou et al).

**Professional Societies**

**American College of Physicians (ACP) and the American Pain Society (APS)**

Clinical practice guidelines published in 2007 concluded that there was insufficient evidence to recommend interferential stimulation for the treatment of LBP (Chou et al).

**Pulsed Electrical Stimulation (PES)**

Pulsed electrical stimulation (PES) is designed to reduce pain and improve function in patients with OA of the knee. The noninvasive device consists of a signal generator, signal applicator, and electrodes encased in either a supportive knee brace or a soft wrap. 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, TKA.

A double-blind, randomized, placebo-controlled trial by Fary et al. (2011) evaluated the effectiveness of PES in the symptomatic management of OA of the knee. Thirty-four patients were randomized to PES and 36 to placebo. Primary outcomes measured pain byVAS. Other measures included WOMAC scores for pain, function, and joint stiffness, Short-Form 36 health survey and perceived effect on QOL 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 OA of the knee.

Farr et al. (2006) reported on a prospective, cohort study examining the use of PES for the treatment of OA of the knee in 288 patients. The device was used for 16-600 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 patients 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 TKA for patients with knee OA. One hundred fifty seven patients who had been referred for a TKA were treated by PES daily for 1 year. They were compared to a matched group of 101 patients. TKA was deferred in 83% of patients in the PES group at 1 year, 75% of patients at 2 years, 65% of patients at 3 years, and 60% of patients at 4 years. In the matched group, TKA was deferred in 67%, 51%, 46%, and 35% of patients at 1-4 years respectively. While the differences in deferral were statistically significant, the investigators concluded that none of the demographic variables studied influenced the need for TKA.

Peripheral Subcutaneous Field Stimulation (PSFS) or Peripheral Nerve Field Stimulation (PNFS)

Subcutaneous stimulation (peripheral nerve field stimulation/PNFS) is a neuromodulation modality that has increased in its utilization during the past decade. This treatment transmits an electrical current via an electrode that has been implanted around the selected peripheral nerve, with the objective of blocking or disrupting 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 LBP. Eighteen patients underwent an uneventful PNFS trial with percutaneous placement of 4 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 2 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 LBP 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 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 LBP 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.

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.

Microcurrent Electrical Nerve Stimulation Therapy (MENS)

Koopman et al. evaluated the efficacy of microcurrent electrical therapy (MCT) in treating aspecific, chronic LBP in a double-blind, randomized, crossover, pilot trial. Ten succeeding patients presenting with nonspecific, chronic LBP in the university setting were included. Patients started with two, 9-day baseline period followed by a 5-day treatment periods. During the treatment periods, either a placebo or MCT (verum) patch was randomly assigned. Mean and worst pain scores were evaluated daily by VAS score. Analgesic use, side effects, and QOL were assessed after each period. Differences between the last 4 days of a treatment period and the baseline period were calculated. Differences between verum and placebo periods per patient were also compared. A 20-mm VAS score reduction was considered clinically relevant. The VAS score was lower during verum treatment, with a reduction in worst pain. Analgesic use decreased during verum treatment, except for nonsteroid anti-inflammatory drug use, which increased. QOL improved during verum treatment. However, none of the findings were statistically significant. The authors concluded that a positive trend in MCT use for aspecific, chronic LBP could be reported. Further investigations are required to evaluate the significance and relevance of this (2009).

Gossreau et al. (2009) assessed the effect of micro-TENS in reducing neuropathic pain in patients with painful diabetic neuropathy (PDN) in a placebo-controlled, single-blinded, and randomized trial. Twenty-two diabetic patients were treated with a micro-TENS therapy and 19 patients were treated with a placebo therapy. Treatment duration was 4 weeks with 3 therapeutical settings per week. Standardized questionnaires (Pain Disability Index [PDI], neuropathic
pain score [NPS], Center for Epidemiologic Studies Depression Scale [CES-D]) were used to assess pain intensity, pain disability, as well as QOL at baseline at the end of the treatment period and 4 weeks after treatment termination. Patients with a minimum of 30% reduction in NPS were defined as therapy responders. After 4 weeks of treatment, 6/21 patients in the verum group versus 10/19 patients in the placebo group responded to therapy. The median PDI score after 4 weeks of treatment showed a reduction of 23% in the verum group versus 25% in the placebo group. The differences did not reach statistical significance. The authors concluded that the pain reduction with the applied transcutaneous electrotherapy regimen is not superior to a placebo treatment.

Zuij et al. (2006) evaluated the effect of MENS therapy compared with occlusal splint therapy in temporomandibular disorders (TMD) patients with muscle pain. Twenty TMD patients were divided into 4 groups. One received occlusal splint therapy and MENS (I); other received splints and placebo MENS (II); the third, only MENS (III) and the last group, placebo MENS (IV). Sensitivity derived from muscle palpation was evaluated using a VAS. Results were submitted to analysis of variance (p<0.05). There was a reduction of pain level in all groups: group I (occlusal splint and MENS) had a 47.7% reduction rate; group II (occlusal splint and placebo MENS), 66.7%; group III (MENS), 49.7% and group IV (placebo MENS), 16.5%. In spite of that, there was no statistical difference (analysis of variance / p<0.05) between MENS and occlusal splint therapy regarding muscle pain reduction in TMD patients after four weeks. The authors concluded that there was no statistically significant difference between MENS and occlusal splints effectiveness on pain reduction of masticatory muscles in TMD patients, and it was verified that the least decreasing pain percent occurred when only MENS placebo was employed. Study limitations include small study group and short follow-up period.

MENS therapy has been studied in other small randomized controlled trials and case series for conditions such as delayed onset muscle soreness (Curtis et al. 2010) and diabetes, hypertension, and chronic wounds (Lee, et al. 2009). None of these studies are large controlled trials designed to test the effectiveness of MENS therapy against a placebo device. Therefore, due to the limited evidence in the peer reviewed literature, conclusions cannot be reached regarding the safety, efficacy, or utility of MENS therapy to decrease pain and/or facilitate healing for any condition.

Dorsal Root Ganglion (DRG) Stimulation

Deer et al. conducted an industry-sponsored single arm pilot study to evaluate the efficacy and safety of the Axium DRG system in 10 patients with chronic intractable pain of the trunk and/or limbs. The study was conducted across 4 centers for a period of 4 weeks. The study protocol and lead implantation procedures were similar to those reported by Liem et al. (2013); however, only results of trial DRGS over a period of 3-7 days were reported. On average, there was a 70% reduction in pain following stimulation. Eight of the nine patients experienced a clinically meaningful (>30%) reduction in pain, and 7 of 9 reduced their pain medication utilization. The study did not consider longer term effects with a permanently implanted device. No device-related adverse events were reported. The authors concluded that initial results suggest that stimulation of the DRG can reduce pain in those patients suffering from chronic pain and may offer several potential benefits over other neuromodulation techniques, including the ability to target difficult-to-reach anatomies such as the low back and foot. Limitations of the study include small sample size, non-randomization, and noted no considerations of long term effects with a permanently implanted device (2013).

A multicenter prospective trial was conducted by Liem et al. (2013) to evaluate the clinical performance of a new neurostimulation system designed to treat chronic pain through the electrical neuromodulation of the DRG neurophysiologically associated with painful regions of the limbs and/or trunk. Thirty-two subjects were implanted with a novel neuromodulation device. Pain ratings during stimulation were followed up to 6 months and compared with baseline ratings. Subjects also completed 2 separate reversal periods in which stimulation was briefly stopped in order to establish the effects of the intervention. At all assessments, more than half of subjects reported pain relief of 50% or better. At 6 months postimplant, average overall pain ratings were 58% lower than baseline, and the proportions of subjects experiencing 50% or more reduction in pain specific to back, leg, and foot regions were 57%, 70%, and 89%, respectively. When stimulation was discontinued for a short time, pain returned to baseline levels. Discrete coverage of hard-to-treat areas was obtained across a variety of anatomical pain distributions. Paresthesia intensity remained stable over time and there was no significant difference in the paresthesia intensity perceived during different body postures/positions (standing up vs. lying down). The authors concluded that this trial demonstrated that neurostimulation of the DRG is a viable neuromodulatory technique for the treatment of chronic pain. Additionally, the capture of discrete painful areas such as the feet combined with stable paresthesia intensities across body positions suggest that this stimulation modality may allow more selective targeting of painful areas and reduce unwanted side-effects observed in traditional spinal cord stimulation (SCS). Limitations include small sample size and short duration of follow-up.

Acknowledging their earlier research, Liem et al. reported on the maintenance of pain relief, improvement in mood, and QOL over 12 months. Subjects with intractable pain in the back and/or lower limbs were implanted with an active neurostimulator device. Up to 4 percutaneous leads were placed epidurally near DRGs. Overall, pain was reduced by 56% at 12 months post-implantation, and 60% of subjects reported greater than 50% improvement in their pain. Pain localized to the back, legs, and feet was reduced by 42%, 62%, and 80%, respectively. Measures of QOL and mood...
were also improved over the course of the study, and subjects reported high levels of satisfaction. Importantly, excellent pain-paresthesia overlap was reported, remaining stable through 12 months. The authors concluded that despite methodological differences in the literature, DRG-SCS appears to be comparable to traditional SCS in terms of pain relief and associated benefits in mood and QOL. Its benefits may include the ability to achieve precise pain-paresthesia concordance, including in regions that are typically difficult to target with SCS, and to consistently maintain that coverage over time. However, long-term evaluations of the results, larger study group size, and prospective randomized studies are still needed (2015).

Schu et al. (2015) conducted a retrospective review of data from patients with groin pain of various etiologies treated using neuromodulation of the DRG. Twenty-nine patients with neuropathic groin pain were reviewed. Patients underwent trial therapy where specifically designed leads were implanted at the target DRGs between T12 and L4. Patients who had a successful trial (> 50% improvement) received the fully implantable neuromodulation system. Pain scores were captured on a VAS at baseline and at regular follow-up visits. Twenty-five patients (86.2%) received fully implantable neurostimulators, and the average follow-up period was 27.8 ± 4.3 weeks. The average pain reduction was 71.4 ± 5.6%, and 82.6% (19/23) of patients experienced a > 50% reduction in their pain at the latest follow-up. Individual cases showed improvement with a variety of etiologies and pain distributions; a subanalysis of postherniorrhaphy cohort also showed significant improvement. The authors concluded that early findings suggest that neuromodulation of the DRG may be an effective treatment for chronic neuropathic pain conditions in the groin region. This technique offers a useful alternative for pain conditions that do not always respond optimally to traditional SCS therapy. Neuromodulation of the DRG provided excellent cross-dermatomal paresthesia coverage, even in cases with patients with discrete pain areas. The therapy can be specific, sustained, and independent of body position. Study limitations include non-randomization and small sample size.

A prospective, randomized, multi-center, controlled clinical trial to assess the safety and efficacy of the Spinal Modulation™ AXIUM™ Neurostimulator System in the treatment of chronic pain (ACCURATE Trial, NCT01923285) was competed in October 2016. Study results have not yet been posted. Additional information is available at www.clinicaltrials.gov.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Functional Electrical Stimulator (FES) devices, such as the Parastep, that have been proposed for restoring ambulation to paraplegics are regulated by the FDA’s premarket approval (PMA) process.

Several FES devices have been approved by the FDA under product code GZI. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 15, 2017)

Interferential stimulators (IFS) 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 IFS devices is too extensive for inclusion in this report. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 15, 2017)

Neuromuscular stimulators that restore ambulation to paraplegics are regulated as Class III or high-risk devices by the U.S. Food and Drug Administration (FDA). The Parastep I received premarket approval from the FDA in April 1994 under Application #P900038. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmac/pma.cfm?id=P900038. (Accessed February 15, 2017)

The WalkAide device received 510(k) approval September 21, 2005, as a neuromuscular functional stimulator to electrically stimulate the muscles that cause ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. The device is intended to counteract foot drop by producing dorsiflexion of the ankle during the swing phase of the gait. 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. Additional information on the device is available at: http://www.accessdata.fda.gov/cdrh_docs/pdfs/K052329.pdf. (Accessed February 15, 2017)

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 disuse atrophy, maintain or increase joint range of motion and increase local blood flow. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdfs/K053468.pdf. (Accessed February 15, 2017)
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 February 15, 2017) 


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 February 15, 2017) 

ERGYS (also known as the TTI Rehabilitation Gym System) was approved as a powered muscle stimulator by the FDA under 510(k) number K841112 on April 4, 1984. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K841112. (Accessed February 15, 2017) 

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 February 15, 2017) 

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 February 15, 2017) 

Peripheral Subcutaneous Field Stimulation (PSFS) or Peripheral Nerve Field Stimulation (PNFS) using a fully implantable system is not currently approved by the FDA. 

The CyMedica e-vive™ System was approved through 510(k) on December 1, 2016. Using advanced NMES, it is intended to be used at home to strengthen muscles pre-total knee replacement. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K163067. (Accessed April 26, 2017) 

Microcurrent Electrical Nerve Stimulation (MENS) device are categorized as TENS devices intended for pain relief. They are regulated by the FDA’s premarket approval (PMA) process. 

The AXIUM™ Neurostimulator System (St. Jude Medical/Abbott) is used to help adult patients manage their moderate to severe chronic intractable pain of the lower limb. The system includes an implanted signal generator, 1-4 implanted leads, and two controllers. It received FDA approval on February 26, 2016. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf15/P150004A.pdf. (Accessed March 8, 2017) 

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) 

Medicare covers neuromuscular electrical stimulation (NMES) and functional electrical stimulation (FES) when criteria are met. See the National Coverage Determinations (NCDs) for Neuromuscular Electrical Stimulation (NMES) (160.12) and Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13). Local Coverage Determinations (LCDs) do not exist at this time. 

Medicare does not have an NCD for interferential therapy (IFT). LCDs exist; see the LCDs for Medicine: Physical Therapy-Outpatient, Outpatient Occupational Therapy, Outpatient Physical Therapy and Outpatient Physical and Occupational Therapy Services. 

Medicare does not have an NCD for pulsed electrical stimulation (PES). LCDs do not exist at this time. 

Medicare does not have an NCD for peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS). LCDs exist; see LCDs for Non-Covered Services, Peripheral Nerve and Peripheral Nerve Field Stimulation and Services That Are Not Reasonable and Necessary.
Medicare does not have a National Coverage Determination (NCD) for microcurrent electrical nerve stimulation (MENS) therapy. Local Coverage Determinations (LCDs) do not exist at this time.
(Accessed April 6, 2017)

Medicare does not have an NCD for dorsal root ganglion (DRG) stimulation. LCDs do not exist at this time.
(Accessed March 10, 2017)

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**

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| 08/01/2017 | Revised coverage rationale:  
  - Modified existing unproven/not medically necessary statements; added language to clarify the procedures are unproven/not medically necessary for treating the listed indication(s)  
  - Added language to indicate:  
    - Microcurrent electrical nerve stimulation (MENS) therapy is unproven and not medically necessary  
    - There is insufficient evidence to conclude that microcurrent electrical nerve stimulation is safe and effective  
    - Robust clinical trials are needed to evaluate this therapy in comparison to other types of treatment  
  - Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary  
    - There is limited evidence in the peer reviewed literature to support that DRG stimulation will improve health outcomes in patients with pain  
    - Randomized controlled trials assessing larger patient groups and long-term follow up are needed to further clarify its role  
    - A description of dorsal root ganglion neurostimulation devices is located in the U.S. Food and Drug Administration (FDA) section of the policy |

**Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation**

UnitedHealthcare Commercial Medical Policy  
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Effective 08/01/2017
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<td>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references</td>
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<td>• Archived previous policy version 2017T0126U</td>
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