UnitedHealthcare Oxford

UnitedHealthcare® Oxford
Clinical Policy

ELECTRICAL STIMULATION FOR THE TREATMENT OF PAIN AND MUSCLE REHABILITATION

Policy Number: DME 035.19 T2 **Effective Date**: January 1, 2019

Instructions for Use

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Related Policies
None

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	Durable medical equipment (DME)[1]
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes
Precertification with Medical Director Review Required	No
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Home
Special Considerations	[1]Refer to the Member's certificate/evidence of coverage, health benefits plan, or benefit rider documentation to determine DME benefit coverage.

COVERAGE RATIONALE

Functional electrical stimulation (FES) is proven and medically necessary as a component of a comprehensive rehabilitation program in members with lower limb paralysis due to spinal cord injury (SCI) when all of the following criteria are met:

- Demonstration of 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;
- Demonstration of brisk muscle contraction;
- Demonstration of sensory perception sufficient for muscle contraction;
- Demonstration of a high level of motivation, commitment and cognitive ability for device use;
- Ability to transfer independently;
- Demonstration of independent standing tolerance for at least 3 minutes;
- Demonstration of hand and finger function to manipulate controls;
- Post-recovery from SCI and restorative surgery of at least 6 months;
- Absence of hip and knee degenerative disease;
- Absence of history of long bone fracture secondary to osteoporosis

Neuromuscular electrical stimulation (NMES) is proven and medically necessary when nerve supply to the muscle is intact and origin of the condition is non-neurological for the following indications:
- Disuse muscle atrophy
- Wrist and finger function for partial paralysis following stroke
- Prevention or correction of shoulder subluxation for partial paralysis following stroke

The following are unproven and not medically necessary due to insufficient evidence of efficacy:
- FES for treating ANY other indication not listed above.
- NMES for treating ANY other indication not listed above.
- Interferential therapy (IFT) for treating musculoskeletal disorders/injuries, or to facilitate healing of nonsurgical soft tissue injuries or bone fractures.
- Pulsed electrical stimulation (PES)
- Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS)
- Microcurrent electrical nerve stimulation (MENS)
- Percutaneous electrical nerve stimulation (PENS) or percutaneous neuromodulation therapy (PNT)
- Dorsal root ganglion (DRG) stimulation
- Scrambler Therapy (ST)

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 may apply.

CPT Code	Description
0278T	Transcutaneous electrical modulation pain reprocessing (e.g., scrambler therapy), each treatment session (includes placement of electrodes)
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
64999	Unlisted procedure, nervous system

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

HCPCS Code	Description
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
E0764	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
E1399	Durable medical equipment, miscellaneous
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8682	Implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

HCPCS Code	Description
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
S8130	Interferential current stimulator, 2 channel
S8131	Interferential current stimulator, 4 channel

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)

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. (Hayes, 2017).

Neuromuscular Electrical Stimulation (NMES)

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.

Interferential Therapy (IFT)

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 (TENS). (Chou et al. 2007)

Pulsed Electrical Stimulation (PES)

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)

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)

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 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™.

Percutaneous Electrical Nerve Stimulation (PENS)

PENS is a conservative, minimally invasive treatment for pain in which acupuncture-like needles connected through a cable to an external power source are inserted into the skin. Needle placement is near the area of pain and is percutaneous instead of cutaneous (e.g., TENS). PENS electrodes are not permanently implanted as in spinal cord stimulation. The mechanism of action of PENS is theorized to modulate the hypersensitivity of nerves from which the persistent pain arises, potentially involving endogenous opioid-like substances. The term percutaneous neuromodulation therapy (PNT) is sometimes used interchangeably with PENS. However, reports indicate PNT is a variant of PENS in which electrodes are placed in patterns that are uniquely different than placement in PENS. (Hayes, 2018)

Dorsal Root Ganglion Stimulation

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 (for example, Axium™ or the next-generation implantable pulse generator Proclaim™), physicians are able to directly treat targeted areas of the body where pain occurs. (St. Jude Medical, 2018)

Scrambler Therapy

Scrambler Therapy (ST) (also referred to as Calmare Pain Therapy [Calmare Therapeutics Inc.] or transcutaneous electronic modulation pain reprocessing), is a noninvasive, transdermal treatment designed for the symptomatic relief of chronic pain. Treatment is performed by applying electrodes corresponding to the dermatome on the skin just above and below the area of pain. The device provides electrical signals via the electrodes presenting nonpain information to the painful area using continuously changing, variable, nonlinear waveforms. (Hayes, 2018)

CLINICAL EVIDENCE

Functional Electrical Stimulation (FES)

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

Hayes performed evidence review from eight studies that evaluated FES for treatment of foot drop in patients with multiple sclerosis (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 2017)

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 RCTs 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 RCT- by El-Shamy and Abdelaal investigated 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 successive 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 ± 0.88 and 9.16 ± 0.65 mL/kg per minute for the study and control groups, respectively. The authors concluded that WalkAide FES may be a useful tool for improving gait pattern and energy expenditure in children with hemiplegic CP. The study was limited to a small sample size.

de Sousa et al. (2016) conducted a blinded, randomized, multi-institutional controlled trial to determine whether active FES cycling as a supplement to standard care would improve mobility and strength more than standard care alone in individuals with a sub-acute acquired brain injury caused by stroke or trauma. The control group (n=20) received standard care, which consisted of a minimum of one-on-one therapy with a physiotherapist at least 1 hour per day. In addition, participants could join group exercise classes or have another hour of one-on-one therapy, if available. The study group (n=20) received an incremental progressive, individualized FES cycling program 5 times a week for 4 weeks, along with standard therapy. The primary outcomes measured were mobility and strength of the knee extensors of the affected lower limb. The secondary outcomes were strength of key muscles of the affected lower limb, strength of the knee extensors of the unaffected lower limb, and spasticity of the affected plantar flexors. On admission to the study most participants could not walk or required a high level of assistance to walk/transfer. Only 2 individuals could ambulate without assistance at the end of 4 weeks. The mean composite score for affected lower limb strength was 7 out of 20 points, reflecting severe weakness. The authors concluded that 4 weeks of FES cycling in addition to standard therapy does not improve mobility in people with a sub-acute acquired brain injury. Further studies could clarify the effects of FES cycling on strength, although the clinical significance may be limited without its accompanying impact on mobility.

Fossat et al. (2018) investigated whether early in-bed leg cycling plus ES of the quadriceps muscles added to standardized early rehabilitation would result in greater muscle strength at discharge from the ICU in a single center blinded RCT enrolling 314 critically ill adult patients. Patients were randomized to early in-bed leg cycling plus ES of the quadriceps muscles added to standardized early rehabilitation (n=159) or standardized early rehabilitation alone (usual care, n=155). The primary outcome was muscle strength at discharge from the ICU assessed by physiotherapists blinded to treatment group using the Medical Research Council grading system (score range, 0-60 points; a higher score reflects better muscle strength). Functional autonomy and health-related QOL were assessed at 6 months. Of the 314 participants, 312 completed the study and were included in the analysis. The median global Medical Research Council score at ICU discharge was higher in the usual care group than in the intervention group, scoring 51 and 48, respectively. There were no significant differences between the groups at 6 months. The authors concluded that adding early in-bed leg cycling exercises and ES of the quadriceps muscles to a standardized early rehabilitation program did not improve global muscle strength at discharge from the ICU (NCT02185989). (Accessed October 22, 2018)

Tan et al. (2016) performed an observational randomized study on 58 patients recovering from stroke to assess the effects of FES on walking function based on normal gait pattern. Participants were randomly divided into 3 groups: four-channel FES group (group A, n=29), single-channel FES group (group B, n=15) and placebo electrical group (group C, n=14) at the rate of 2:1:1. All received the standardized rehabilitation program. The four-channel and single-channel FES groups received treatment based on normal gait pattern. The placebo electrical group received the same ES as the four-channel FES group, but without current output when stimulating. After 3 weeks of treatment and statistically significant improvement in all 3 groups, the authors concluded FES based on normal gait pattern could improve walking function in individuals recovering from stroke.

Pool and colleagues 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 the Walk Aide device 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 that affect gait in children with unilateral spastic CP. The study was limited to a small sample size. (2014)

Broekmans et al. (2011) conducted a RCT involving 36 persons with MS to examine the effect(s) of unilateral long-term (20 weeks) standardized resistance training with and without simultaneous ES 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 ES does not further improve training outcome.

Kadoglou et al. performed a randomized, placebo-controlled study to investigate the effects of FES on the lower limbs as an alternative method of training in patients with chronic heart failure (HF). Participants deemed stable (n=120) (defined by New York Heart Association (NYHA) class II/III and mean left ventricular ejection fraction (LVEF) of 28 ± 5%), were randomly selected for either a 6-week FES training program or placebo. Patients were followed for up to 19 months for death and/or hospitalization due to HF decompensation. At baseline, there were no significant differences in demographic parameters, HF severity, or medications between groups. During a median follow-up of 383 days, 14 patients died (11 cardiac, three non-cardiac deaths), while 40 patients were hospitalized for HF decompensation. Mortality did not differ between groups, although the HF-related hospitalization rate was significantly lower in the FES group. The latter difference remained significant after adjustment for prognostic factors: age, gender, baseline NYHA class and LVEF. Compared to placebo, FES training was associated with a lower occurrence of the composite endpoint (death or HF-related hospitalization) after adjustment for the above-mentioned prognostic factors. The authors concluded that 6 weeks of FES training in individuals with chronic HF reduced the risk of HF-related hospitalizations without affecting the mortality rate. The beneficial long-term effects of this alternative method of training require further investigation. (2017)

A pilot study by Ratchford et al. (2010) evaluated the safety and preliminary efficacy of home FES cycling in 5 patients with chronic progressive MS (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 MS 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 Care 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 ADL. (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 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, 1997 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 SCIs (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.

Professional Societies

American Occupational Therapy Association (AOTA)

The AOTA practice guidelines for adults with stroke state that for improved occupational performance of individuals with motor impairments, there is high certainty based on evidence that the use of ES has a moderate net benefit. The guidelines also state that regarding electrical stimulation to improve activity–participation, the evidence is weak regarding the therapy improves patient outcomes. (Wolf and Nilsen, 2015)

Neuromuscular Electrical Stimulation (NMES) for Muscle Rehabilitation

Although the evidence is limited, NMES for the treatment of disuse atrophy in individuals 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.

A 2018 Cochrane review by Hill et al. evaluated the effects of NMES, either alone or concurrently with conventional exercise therapy, to determine if this treatment might improve the overall physical condition and health-related QOL in people with chronic obstructive pulmonary disease (COPD). Nineteen studies met the inclusion criteria, of which 16 contributed data on 267 individuals with COPD. Of these 16 studies, 7 explored the effect of NMES versus usual care. Nine explored the effect of NMES plus conventional exercise training vs conventional exercise alone. The reviewers concluded that NMES, when applied alone, increased quadriceps force and endurance, 6-minute walking distance, time to symptom limitation exercising at a submaximal intensity, and reduced the severity of leg fatigue on completion of exercise testing. Evidence quality was considered low or very low due to risk of bias within the studies, imprecision of the estimates, small number of studies and inconsistency between the studies. The inclusion of future studies into this review is likely to change the results.

Knutson et al. (2016) evaluated whether contralaterally controlled functional electrical stimulation (CCFES) or cyclic neuromuscular electrical stimulation (cNMES) was more effective for post-stroke upper limb rehabilitation in an interventional, phase II, randomized trial conducted at a single institution (NCT00891319). Stroke patients (n=80) with chronic (> 6 months) moderate to severe upper extremity (UE) hemiparesis were randomized into 2 groups, receiving 10 sessions/week of CCFES- or cNMES-assisted hand opening exercise at home plus 20 sessions of functional task practice in the lab over 12 weeks. The primary outcome was improvement in Box and Blocks Test (BBT) score at 6-months post-treatment, with UE Fugl-Meyer motor assessment (UEFMA) and Arm Motor Abilities Test (AMAT) also being measured. Evaluation of participants occurred at baseline, every 3 weeks during the treatment period, at end-of-treatment, and 2, 4, and 6 months post-treatment by a blinded assessor. At 6-months post-treatment, the CCFES group had greater improvement than the cNMES group on the BBT, 4.6 versus 1.8, respectively, and a between-group difference of 2.8. No significant between-group difference was found for the UEFMA or AMAT. The authors concluded that 12 weeks of CCFES therapy resulted in improved manual dexterity compared to cNMES in stroke survivors experiencing chronic moderate to severe hand impairment, with advantage given to those whose impairment was moderate and were < 2 years post-stroke. The translatability of CCFES therapy to other research sites and to clinical practice still has not been established.

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 RCTs 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.

Talbot et al. (2017) conducted a pilot study to compare the effects of a home-based NMES rehabilitation program plus the traditional military amputee rehabilitation program (TMARP) vs. the effects of TMARP alone on quadriceps muscle strength, functional mobility, and pain in military service members after a combat-related lower extremity amputation. In total, 44 participants with a unilateral transtibial amputation were randomly assigned to the TMARP plus NMES (n=23) or to TMARP alone (n=21). Both groups received 12 weeks of the traditional amputee rehabilitation, including pre- and post-prosthetic training. Those in the NMES group also received 12 weeks of NMES. Participants were tested at 3-week intervals during the study for muscle strength and pain. For functional measures, they were tested after receiving their prosthesis and at study completion (weeks 6 and 12). In both groups, residual limb quadriceps muscle strength and pain severity improved from baseline to 12 weeks. The NMES plus TMARP group showed greater strength than the TMARP alone group at 3 weeks, before receiving the prosthesis. However, 6 weeks post-prosthesis, there was no group difference in the residual limb strength. Functional mobility improved in both groups between weeks 6 and 12 with no difference between the 2 treatment groups. The authors concluded that a home-based NMES intervention with TMARP worked at improving residual limb strength, pain, and mobility. While NMES seemed most effective in minimizing strength loss in the amputated leg pre-prosthesis, further research on amputation rehabilitation is warranted, as NMES may accelerate recovery (NCT00942890). (Accessed October 22, 2018)

A RCT by Pool et al. evaluated whether 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 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 increased muscle volumes and dorsiflexion strength not only when compared to their baseline values but also when compared to the control group at week 8. At week 14, both tibialis anterior and lateral gastrocnemius volumes in the treatment group remained significantly increased when compared to their baseline values. However, only lateral gastrocnemius volumes had significantly greater values when compared to the control group at week 14. There were no between group differences in the clinical measures for lower limb selective motor control at weeks 8 and 14. The authors concluded that 8 weeks of daily NMES-assisted gait increases muscle volume and strength of the stimulated ankle dorsiflexors in children with unilateral spastic CP. These changes are use-dependent and do not carry over after the 8-week treatment period. Gastrocnemius volume also increased post-treatment with carryover at week 14. (2016)

Lin et al. (2011) completed a single-blinded, RTC to investigate the long-term efficacy of NMES in enhancing motor recovery in the UEs 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 UE section of the FMA, and the Modified Barthel Index were used to assess the results. Significant improvements were found in both groups in terms of FMA, 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 three weeks of NMES to the affected UE 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 RCT by Shen et al. (2015), CCFES was compared to NMES as an innovative method to improve UE 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 UE (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 UE 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 UE function in patients with stroke.

Hsu et al. (2010) conducted a RCT to investigate the effects of different doses of NMES on UE 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 RCT, 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 daily 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 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)

There are also studies that NMES can be effective when used for quadriceps strength training following anterior cruciate ligament (ACL) reconstruction or prior TKA. In a small RCT 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 the 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 2010, Weber et al. conducted a RCT 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.

Patsaki et al. (2017) studied the effects of NMES along with individualized rehabilitation on muscle strength of ICU survivors. Following ICU discharge, 128 patients were randomized to either daily NMES sessions and individualized rehabilitation (NMES group) or to the control group. Muscle strength was assessed by the Medical Research Council (MRC) score and hand grip at hospital discharge. Secondary outcomes were functional ability and hospital length of stay. The authors found that NMES and personalized physiotherapy in ICU survivors did not result in greater improvement of muscle strength and functional status at hospital discharge. However, they concluded that NMES may be effective in this subset of patients, and that the potential benefits of rehabilitation strategies should be explored in larger numbers in future studies (NCT01717833). (Accessed October 22, 2018)

NICE guidance on transcutaneous NMES for oropharyngeal dysphagia found current evidence on efficacy to be limited in quality. They did not cite any major safety concerns, although they considered the safety evidence to be limited in both quality and quantity. NICE states that this technology should only be used with special arrangements for clinical governance, consent and audit or research; and encourages further research into transcutaneous NMES for this condition, which clearly documents indications for treatment and details of patient selection. (2014)

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 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.

Musculoskeletal Pain

To evaluate the effectiveness of passive physical modalities (which included IFT) on soft tissue injuries of the shoulder, Yu et al. (2015) conducted a systematic review of literature published between January 1, 1990, and April 18, 2013. RCTs and cohort and case-control studies were eligible. Of the 22 eligible articles, 11 studies were found to have a low risk of bias and so were analyzed, although the collective number of patients within the 11 studies was not cited. IFT was one of multiple modalities that were ineffective in reducing shoulder pain. The authors concluded that most passive physical modalities, including IFT, do not benefit patients with subacromial impingement syndrome.

In 2010, Fuentes and colleagues published a systematic review and meta-analysis of studies evaluating the effectiveness of IFS for treating pain. A total of 20 studies met the following inclusion criteria: RCT; 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.

Dissanayaka et al. (2016) compared the effectiveness of TENS and IFT in a single-blind RCT on individuals with myofascial pain syndrome (MPS). The aim of this study was to compare the effectiveness of these treatment modalities both in combination with hot pack, myofascial release, AROM exercise, and a home exercise program on MPS patients with upper trapezius myofascial trigger point. A total of 105 patients with an upper trapezius myofascial trigger point were randomly allocated to 3 groups, 3 therapeutic regimens-control-standard care (hot pack, AROM exercises, myofascial release, and a home exercise program with postural advice), TENS-standard care and IFT-standard care-were administered 8 times during 4 weeks at regular intervals. Pain intensity and cervical range of motions (cervical extension, lateral flexion to the contralateral side, and rotation to the ipsilateral side) were measured at baseline, immediately after the first treatment, before the eighth treatment, and 1 week after the eighth treatment. Immediate and short-term improvements were marked in the TENS group (n=35) compared with the IFT group (n=35) and the control group (n=35) with respect to pain intensity and cervical range of motions. The IFT group showed significant improvement on these outcome measurements than the control group did. The authors concluded that TENS with standard care facilitates recovery better than IFT does in the same combination.

Osteoarthritis (OA)

Gundog et al. (2012) conducted a RCT to compare the effectiveness of IFT to sham IFT for the treatment of OA. Sixty patients were allocated to 3 active IFT groups (40, 100, and 180 Hz), and one sham IFC group. Treatments were administered for twenty minutes each, five times per week, for three 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), 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 IFT groups than in the sham group. The improvement in WOMAC stiffness was observed only in active IFT treatment groups. No significant difference between different amplitude-modulated frequencies of IFT treatments was observed. The authors concluded that the study demonstrated the superiority of the IFT with some advantages on pain and disability outcomes when compared with sham IFT for the management of knee OA. Limitations Author- of the study included small patient population, difficulty finding patients who met inclusion criteria, and short-term follow-up.

Zeng et al. (2015) performed a systematic review and Bayesian network meta-analysis of 27 RCTs over a 30-year period, which compared different electrical stimulation (ES) therapies (high-frequency TENS (h-TENS), low-frequency TENS (l-TENS), NMES, IFC, PES and noninvasive interactive neurostimulation (NIN)) with the control group (sham or no intervention) for relief of knee pain in 1253 patients with OA. The primary goal was to identify whether or not the different ES modalities offered pain management by measuring the degree of pain intensity and the change pain score at last follow-up time point. Of the 6 therapy modalities, IFC was the only significantly effective treatment in both pain intensity and change pain score at last follow-up time point when compared with the control group. In addition, IFC was deemed the best probable option for pain relief among the 6 therapy modalities. The authors' conclusions were that IFC was the most promising for management of knee pain related to OA. The other ES therapies were considered safe for patients with knee OA, although some were considered inappropriate. Study limitations included a small number of included trials as well as heterogeneity of the evidence.

A multi-center, single-blind, RCT 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 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 (AEs). 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 manufacturer sponsoring, 10% drop out rate and the treatment effect did not reflect a sufficient significant difference.

Professional Societies

American Academy of Orthopaedic Surgeons (AAOS)

In its clinical practice guideline on the treatment of OA of the knee, the AAOS cannot recommend for or against the use of physical agents (including electrotherapeutic modalities) due to inconsistent findings. (2013)

Anterior Cruciate Ligament/Meniscectomy/Knee Chondroplasty

Jarit et al. (2003) conducted a randomized, double-blind, placebo-controlled trial of home-based, IFT in 87 patients who had undergone 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 IFT as a treatment to accelerate healing of tibial fractures in a double blind, RCT. 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. IFTs 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 rhythmical massage effect. The control group received no intervention. The data analysis reflected no difference in the time for union in the three groups. The authors concluded that IFT did not reduce healing time for new tibial fractures or prevent nonunion, and that further investigation was recommended.

Low Back Pain

Franco et al. (2016) conducted a double-blind single institution RCT on 148 patients with chronic nonspecific low back pain (LBP) to determine whether IFC before Pilates exercises is more effective than placebo. The primary outcome measures were pain intensity, pressure pain threshold, and disability after 6 weeks of therapy. The study groups consisted of active IFC + Pilates group, and placebo IFC + Pilates group. Eighteen treatment sessions were offered 3 times a week for 6 weeks. Both groups showed significant improvement in outcomes after 6 weeks, with improvements in pain and disability being considered clinically significant as well. However, the authors concluded that active IFC combined with Pilates exercises is no better than placebo IFC plus Pilates. Further studies are suggested.

To assess the influence of TENS and IFC on pain relief and to compare the analgesic efficacy of the 2 modalities, Grabianska et al. (2015) studied 60 patients with 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 IFT 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 IFT 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, RCT on 60 subjects with LBP, evaluating whether the IFT 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 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. 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, 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.

Rajfur et al. (2017) conducted a pilot study to compare the effects of treating LBP using selected electrotherapy methods, assessing the influence of individual electrotherapeutic treatments on reduction of pain, improvement of the range of movement in lower section of the spine, and improvement of motor functions and mobility. Participants were assigned to 6 comparison groups: A - conventional TENS, B - acupuncture-like TENS, C - high-voltage ES, D - IFT stimulation, E - diadynamic current, and F - control group. Of the 127 qualified participants, 123 completed the 3-week study. Authors determined that selected electrical therapies (IFT, TENS< and high voltage ES) appear to be effective in treating chronic LBP.

Professional Societies

American College of Physicians (ACP)

In their clinical practice guideline addressing noninvasive treatments for acute, subacute, and chronic LBP, the ACP states clinicians and patients should initially select non-pharmacologic treatments including but not limited to exercise (e.g., tai chi, yoga, motor control exercise) and multidisciplinary rehabilitation (e.t., electrical stimulation therapies) when managing chronic LBP. (Qaseem et al., 2017)

Pulsed Electrical Stimulation (PES)

PES is designed to reduce pain and improve function in individuals with OA of the knee who do not respond well to nonsteroidal, anti-inflammatory drug (NSAID) treatment or who are not appropriate candidates for, or do not wish to undergo, TKA. The noninvasive device consists of a signal generator, signal applicator, and electrodes encased in either a supportive knee brace or a soft wrap.

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 by VAS. Other measures included WOMAC scores for pain, function, and joint stiffness, and Short-Form 36 (SF-36) health survey, as well as 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. Compared to the control group at 44% improvement, 56% of the PES-treated group achieved a clinically relevant 20-mm improvement in VAS pain score at 26 weeks . Overall, however, 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 in 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 one year. They were compared to a matched group of 101 patients. TKA was deferred in 83% of patients in the PES group at one year, 75% of patients at two years, 65% of patients at three years, and 60% of patients at four years in 60% of patients. 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.

AHRQ conducted a Comparative Effectiveness Review assessing the efficacy of a variety of noninvasive interventions (including but not limited to electrical stimulation techniques [including TENS], NMES, and pulsed electromagnetic field therapy [PEMF]) for treating OA of the knee. RCTs, single-arm, and prospective observational studies were included in the analysis, comparing any of the interventions of interest with placebo (sham) or any other intervention that reported a clinical outcome (including pain, function, and QOL). PEMF showed short term pain relief, but the strength of evidence was considered low. The review found that the evidence was insufficient to draw conclusions about the effectiveness of many interventions, secondary to heterogeneous and low quality studies. Larger randomized controlled trials were suggested. (Newberry et al., 2017)

Professional Societies

American Academy of Orthopaedic Surgeons (AAOS)

In its clinical practice guideline on the treatment of OA of the knee, the AAOS cannot recommend for or against the use of physical agents (including electrotherapeutic modalities) due to inconsistent findings. (2013)

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

PSFS (also referred to as 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 subcutaneously around the selected peripheral nerve, with the objective of blocking or disrupting the normal transmission of pain signals.

van Gorp et al. (2016) conducted a multicenter, RCT investigating the efficacy of subcutaneous stimulation (SubQ) as ADD-ON therapy to traditional spinal cord stimulation (SCS) in treating back pain in failed back surgery syndrome patients. Individuals with a minimal pain score of 50 on a 100 mm VAS for both leg and back pain were eligible. If pain reduction after trial SCS was ≥ 50% for the leg but < 50% for the back, patients received additional SubQ leads and were randomized in a 1:1 ratio in a study arm with subcutaneous leads switched on (SubQ ADD-ON), and an arm with subcutaneous leads switched off (Control). The primary outcome was the percentage of the patients, at 3 months post-implantation, with ≥ 50% reduction of back pain. A total of 97 patients were treated with SCS for leg and back pain. Of these, 52 patients were randomized and allocated to the Control group (n=24) or to the SubQ ADD-ON group (n=28). The percentage of patients with ≥ 50% reduction of back pain was significantly higher in the SubQ ADD-ON group (42.9%) compared to the Control group (4.2%). Mean VAS score for back pain at 3 months was a statistically significant 28.1 mm lower in the SubQ ADD-ON group compared to the Control group. The authors concluded that subcutaneous stimulation as an ADD-ON therapy to SCS is effective in treating back pain in failed back surgery syndrome patients where SCS is only effective for pain in the leg.

McRoberts et al. (2013) conducted a multi-site, 2-phase, crossover RCT evaluating the safety and efficacy of PNfS in 44 patients with localized chronic intractable pain of the back. During phase I, patients rotated through 4 stimulation groups (minimal, subthreshold, low frequency, and standard stimulation). If a 50% reduction in pain was achieved during any of the three active stimulation groups (responder), the patient proceeded to phase II, which began with implant of the permanent system and remained in place for 52 weeks. The primary endpoint was a reduction in pain, assessed by the VAS. Of the 44 patients enrolled, 30 completed phase I. Twenty-four patients were classified as responders in phase I, and 23 received permanent system placement. Significant differences in VAS scores were observed between baseline and all follow-up visits during phase II. The authors concluded that PNfS is safe and effective as an aid in the management of chronic, localized back pain. Limitations to this trial are small study group size.

Yakovlev et al. (2011) evaluated PNFS as an alternative treatment option for patients with postlaminectomy syndrome when conventional treatments did not provide adequate relief of intractable LBP. 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 SCS in patients with post-laminectomy syndrome 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.

To aid in alleviating symptoms associated with opioid withdrawal, a PNFS delivery system known as the NSS-2 Bridge is marketed for use as a non-pharmacologic component of an inpatient or outpatient detoxification treatment program. One single-arm retrospective pilot study has been published (Miranda and Taca, 2017), citing 64 of 73 patients successfully transitioning to medically-assisted treatment after using the device with no reports of AEs. While several guidelines on the management of opioid withdrawal are available, none addressed the use of this type of device for this indication. Prospects for the NSS-2 Bridge System are unclear at this time (Hayes, 2017). Another PNFS system similar to the NSS-2 Bridge is known as the DrugRelief® stimulator. This auricular neurostimulation device is also used to reduce the symptoms of opioid withdrawal during detoxification. At present, there are no studies or published literature relating to this device.

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

Microcurrent Electrical Nerve Stimulation Therapy (MENS)

A 2018 Hayes report evaluated the use of microcurrent electrical therapy (MET) for the treatment of musculoskeletal pain in comparison with usual care. The literature search identified 6 eligible studies that compared MET with an alternative treatment in patients with musculoskeletal pain (lateral epicondylitis, LBP, Achilles tendinopathy, temporomandibular joint pain, and masticatory pain associated with bruxism (teeth grinding)). Evidence was considered to be very low quality. The authors concluded that there is insufficient evidence to assess the efficacy of MET for the treatment of pain associated with any of these conditions due to the paucity of evidence evaluating MET in any one indication. Additionally, the report concluded that there is substantial uncertainty regarding whether MET provides reduction in pain compared with usual care in patients with lateral epicondylitis.

MET was also evaluated by Hayes for the treatment of postoperative pain in adults. The literature search identified only 3 studies that evaluated MET for post-TKA (2 studies) and total hip arthroplasty (1 study). The authors concluded that there is insufficient evidence to evaluate use of MET for this indication, and there is substantial uncertainty regarding whether this technology provides pain relief in adults undergoing total joint arthroplasty. (2018)

Kwon et al. (2017) conducted a prospective, double-blinded, sham-controlled RCT to evaluate the effects of short-term MENS on muscle function in the elderly. A total of 38 healthy elderly participants aged 65 years and above were enrolled and randomly divided into a real MENS or a sham MENS stimulation group. Both groups received stimulation to the 8 anatomical points of the dominant arm and leg during the course of 40 minutes. The researchers' hypothesis was accurate that real MENS was superior to sham in enhancing muscle function in healthy elderly subjects following short term application. Limitations to this study included the lack of definition of the "healthy elderly", short application time of the MENS, and lack of follow-up evaluation. Long-term RCTs with follow-up assessments are needed to confirm these results.

Koopman et al. evaluated the efficacy of MENS 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 periods followed by a 5-day treatment period. 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. All outcome measures demonstrated efficacy with the verum treatment, except for an increase in NSAID use. However, none of the findings were statistically significant. The authors concluded that a positive trend in MENS use for aspecific, chronic LBP could be reported, but that further research is required to evaluate the significance and relevance of these findings. (2009)

Gossreau et al. (2011) conducted a single-blinded, placebo-controlled randomized trial to assess the efficacy of MENS for reduction of painful diabetic neuropathy (PDN) in 41 patients. Participants were divided into 2 groups: 22 treated with MENS therapy and 19 with placebo. Treatment plan was 3 therapeutical setting per week for 4 weeks. Primary outcomes measured included pain intensity, pain disability, and QOL at baseline, and the end of treatment, and 4 weeks post-treatment using standardized questionnaires. Patients with a minimum of 30% reduction in neuropathic pain score (NPS) were defined as therapy responders. After 4 weeks, only 6 of 21 patients in the study group (30%) responded to MENS therapy versus 10 of 19 (53%) of the placebo group. The differences in Pain Disability Index (PDI) for both groups were not statistically significant. The authors concluded that MENS therapy for PDN is not superior to placebo.

Zuim 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: occlusal splint therapy and MENS (group I); occlusal splints and placebo MENS (group II); only MENS (group III) and placebo MENS (group IV). Sensitivity derived from muscle palpation was evaluated using a VAS. There was reduction of pain level in all groups: group I reported a 47.7% reduction rate; group II 66.7%; group III 49.7% and group IV 16.5%. However, the differences between groups relating to TMD muscle pain reduction were not statistically significant after 4 weeks. The authors concluded that MENS was not statistically superior to occlusal splints in the treatment of masticatory muscle pain in TMD patients.,. Study limitations include small study group and short follow-up period.

MENS therapy has been studied in other small RCTs 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.

Percutaneous Electrical Nerve Stimulation (PENS)

A Hayes report evaluated the peer-reviewed literature related to PENS for the treatment of chronic low back pain (CLBP) and PNT for the treatment of low back pain (LBP). Evidence from the available studies (which included 3 RCTs with a range of 34-200 participants and 1 pretest/posttest study) was considered to be fair, poor, or very poor quality. The 3 RCTs evaluated the efficacy and safety of PENS for chronic LBP in adults and remaining study evaluated PNT for subacute radiating LBP. The authors concluded that there was insufficient published evidence to assess the clinical validity of PENS alone or in combination with physical therapy or general conditioning exercise in patients with CLBP. Additionally, the report concluded that there is insufficient published evidence to assess the impact of PNT on health outcomes or patient management for the treatment of LBP. (2018)

Meng et al. (2018) conducted a multicenter RCT to investigate the effects of electroacupuncture (EA) on reducing inflammatory reaction and improving intestinal dysfunction in patients with sepsis-induced intestinal dysfunction with syndrome of obstruction of the bowels. A total of 71 patients were randomly assigned to control group (n=36) and treatment group (n=35). Patients in the control group were given conventional therapies including fluid resuscitation, anti-infection, vasoactive agents, mechanical ventilation, supply of enteral nutrition, and glutamine as soon as possible. In addition to conventional therapies, patients in treatment group underwent 20 minutes of EA twice a day for 5 days. At baseline, day 1, day 3, and day 7 after treatment, biomarkers assessing intestinal inflammation and dysfunction were measured and recorded, respectively. Additionally, days on mechanical ventilation (MV), length of stay in intensive care unit (ICU), and 28-day mortality were also recorded. The authors concluded that EA, as a supplement to conventional therapy, can reduce inflammatory reaction and has protective effects on intestinal function than conventional therapy alone in patients with sepsis-induced intestinal dysfunction with syndrome of obstruction of the bowels. However, there were no significant differences identified between the 2 groups relative to number of days on MV, length of stay in ICU, and 28-day mortality. Limitations to this study include small sample size and single-center investigation. Further studies are required.

Rossi et al. (2016) conducted a multicenter, prospective, observational study to evaluate the short- and long-term efficacy of a single probe and single shot PENS approach to treat chronic neuropathic pain. Seventy-six patients affected by neuralgia were enrolled in the study and divided into 3 groups depending on the etiology of the neuralgia (21 herpes zoster infection, 31 causalgia, 24 postoperative pain). In the study, Numerical Rating Scale (NRS) and Neuropathic Pain Scale (NPS) were assessed at baseline, 60 minutes after PENS, 1 week, and 1, 3, and 6 months post-therapy. Perceived health outcome was measured with Euroqol-5 dimension (EQ-5D) questionnaire at baseline and at 6 months. Pain assessment ratings decreased significantly after 60 minutes of PENS therapy and the reduction remained constant throughout the follow up period. Perceived health outcome measured with EQ-5D increased significantly from baseline. The authors concluded that PENS therapy produced significant and long-lasting pain relief in chronic peripheral neuropathic pain of different etiologies. The study limitations included small sample size, non-randomized observational study, short follow up period, and high prevalence of post-herpetic and occipital neuralgias.

In 2011, Wanich and colleagues conducted a RCT to study the use of the Deepwave PNT system in patients who underwent primary total knee replacement (TKR) surgery. Trial participants (n=23) were categorized into 2 groups (experimental or control). Following surgery, patients underwent either Deepwave or sham treatments. A Brief Pain Inventory questionnaire and the amount of all pain medications taken were recorded. The study results demonstrated a significant reduction in patient's subjective rating of pain and VAS score in the experimental group ($p < 0.05$), with a trend toward decreased opioid use but this was not statistically significant ($p = 0.09$). The authors concluded that the Deepwave device was effective in reducing the subjective measures of pain with a trend toward decreased opioid use in patients following TKR. Details regarding the duration of treatments or the length of follow up were not documented.

Raphael et al. (2011) conducted a randomized double-blind sham-controlled crossover trial on 31 patients suffering from chronic pain with surface hyperalgesia to investigate the efficacy of PENS. The study results demonstrated statistically significant improvements from pre-therapy ratings and assessment of pain in the PENS group versus the sham group using the numerical rating scale (NRS) and the pain pressure threshold (PPT). The authors concluded that PENS therapy appeared to be effective in providing short-term pain relief in chronic pain conditions; however, studies, involving larger sample sizes and longer follow-up were recommended.

Mi et al. (2018) conducted a randomized observational trial to evaluate the effect of transcutaneous electrical acupoint stimulation (TEAS) on dosages of anesthetic and analgesics as well as the quality of recovery during the early period after laparoscopic cholecystectomy. One hundred patients who underwent laparoscopic cholecystectomy with grade I and II of the American Society of Anesthesiologists criteria were evenly and randomly assigned into an observation group and a control group. The patients in the observation group were treated with TEAS from 30 minutes prior to anesthesia induction to the end of operation. The patients in the control group received stimulation electrode(s) in the corresponding points without ES for the same time period. Researchers concluded that TEAS can reduce the dosage of anesthetic and analgesic delivered intraoperatively, as well as improve the quality of recovery during the early period after laparoscopic cholecystectomy.

In 2013, NICE published guidance related to the use of PENS to control neuropathic pain. The guidance states, "The current evidence on the safety of PENS for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term. Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit." The guideline also indicates that NICE encourages further research into PENS for refractory neuropathic pain, particularly to provide more information about selection criteria and long-term outcomes, with clear documentation of the indications for treatment.

Professional Societies

American Academy of Neurology (AAN), American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), American Academy of Physical Medicine and Rehabilitation (AAPMR)

In a joint guideline report on the treatment of painful diabetic neuropathy (PDN), the AAN, AANEM, and AAPMR concluded that PENS should be considered for the treatment of PDN. (Bril et al., 2011)

While some studies have compared the effectiveness of PENS to placebo, the overall quality of the evidence is weak and quite limited. Further robust studies are needed to evaluate the efficacy of this therapy for chronic pain.

Dorsal Root Ganglion (DRG) Stimulation

Deer et al (2017) conducted a prospective, multicenter, randomized comparative effectiveness trial (known as the ACCURATE trial) in 152 subjects diagnosed with complex regional pain syndrome (CRPS) or causalgia in the lower extremities. Subjects received neurostimulation of the DRG or dorsal column (spinal cord stimulation, SCS) via the Axium™ DRG system. The primary end point was a composite of safety and efficacy at 3 months, and subjects were assessed through 12 months for long-term outcomes and AEs. The predefined primary composite end point of treatment success was met for subjects with a permanent implant who reported 50% or greater decrease in VAS score from pre-implant baseline and who did not report any stimulation-related neurological deficits. No subjects reported stimulation-related neurological deficits. The percentage of subjects receiving ≥ 50% pain relief and treatment success was greater in the DRG arm (81.2%) than in the SCS arm (55.7%) at 3 months. Device-related and serious AEs were not different between the 2 groups. DRG stimulation also demonstrated greater improvements in QOL and psychological disposition. Finally, subjects using DRG stimulation reported less postural variation in paresthesia and reduced extraneous stimulation in non-painful areas, indicating DRG stimulation provided more targeted therapy to painful parts of the lower extremities. The researchers concluded that DRG stimulation provided a higher rate of treatment success with less postural variation in paresthesia intensity compared to SCS.

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 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.

Hayes performed an evidence review from 3 studies that evaluated DRG stimulation for treatment of CRPS in adults. Overall, a very-low-quality body of evidence suggests that DRG stimulation may result in treatment success, reductions in pain, and improvements in QOL compared with baseline assessments or SCS treatment. However, this body of evidence is limited by individual study limitations, limited quantity of evidence, and the availability of a single study comparing groups of patients that received DRG stimulation or SCS. In addition, current evidence suggests a potential safety concern for procedure-related AEs with DRG stimulation. Currently, there is insufficient evidence to draw conclusions regarding the safety and effectiveness of DRG stimulation for the treatment of CRPS in adults. (2017)

Several clinical trials studying DRG stimulation in patients with various conditions are active or recruiting. For more information, please go to www.clinicaltrials.gov. (Accessed October 22, 2018)

Scrambler Therapy (ST)

Separate Hayes reports on the management of pain relating to cancer and non-cancer conditions examined clinical studies (8 studies, n=11-41 for cancer related; 7 studies, n=30-226 for non-cancer related) where Calmare/Scrambler Therapy (ST) was utilized. It was determined that the body of evidence, considered low or very low quality, is insufficient to draw conclusions on the safety and efficacy of Calmare/ST for pain management with any condition. (2018)

Kashyap et al. (2017) studied the effect of ST on patients with chronic cancer pain in a prospective, observational study. A total of 20 patients aged 18-70 years with a life expectancy of >3 months having bony, neuropathic, or mixed type of pain unresponsive to oral analgesics were included. A total of 12 sessions of ST were planned, 10 sessions on consecutive days and one session each on two follow-up visits after 1 week each. Each session lasted for 40 min. Pain relief and QOL according to the World Health Organization QOL were recorded as primary outcome variables. All patients had good pain relief and improvement in all four domains of QOL. Pain scores decreased significantly after each session and at each follow-up. Patients also showed significant improvement in physical, psychological, social, and environmental health post-therapy. The authors concluded that ST offers a promising role as an adjunct to pharmacological therapy for the treatment of chronic drug-resistant cancer pain; it may bring down analgesic drug requirements significantly and improve QOL in cancer patients. Larger prospective, randomized multicenter studies are needed to validate the findings of the small pilot studies published in literature so far.

Compagnone and Tagliaferri (2015) conducted a multicenter, retrospective analysis on the safety and efficacy of ST after 10 sessions. All the patients (n=201) were suffering from chronic neuropathic pain of multiple etiologies. The mean number of sessions per patient was 10, but 39 subjects had complete absence of pain sooner and used fewer sessions. Seven patients stopped treatment due to lack of results, and 2 withdrew for personal reasons not ascribable to the treatment. Stimulation pain score of 0 during treatment, and not just pain reduction, is believed to be a predictor of long term effectiveness. The authors concluded that ST is an efficient and safe alternative for several different types of refractory chronic neuropathic pain, with a very rare possibility of adverse events. Further studies are needed to optimize electrode positioning and correct fine-tuning of stimulation intensity.

Majithia et al. conducted a review to further evaluate what is known regarding the mechanics of ST and to investigate the preliminary data pertaining to the efficacy of this treatment modality. 20 reports of varying scientific quality were identified as having been published regarding this device; all but one small study, published only as an abstract, provided results that appear positive. The reviewers concluded that the positive findings from preliminary studies with ST support that this device provides benefit for patients with refractory pain syndromes. Larger, randomized studies are required to further evaluate the efficacy of this approach. (2016)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Functional Electrical Stimulation (FES) Devices

Products used for FES are extensive. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed October 1, 2018)

Neuromuscular Electrical Stimulation (NMES) for Muscle Rehabilitation Devices

Products used for NMES for muscle rehabilitation are extensive. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed October 1, 2018)

Interferential Therapy (IFT) Devices
Products used for IFT are extensive. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed October 1, 2018)

Pulsed Electrical Stimulation (PES) Devices
There are multiple products used for PES. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed October 1, 2018)

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

The NSS-2 System, a PNFS system marketed as an aid to reduce the symptoms of opioid withdrawal, was FDA approved on 11/15/17. For more information, please go to:
https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170018.pdf. (Accessed October 1, 2018)

The DrugRelief® auricular stimulator, a PNFS system marketed as an aid to reduce symptoms of opioid withdrawl, was FDA approved on 5/2/18 (Product Code PZR). For more information, please go to:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173861. (Accessed September 28, 2018)

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

Percutaneous electrical nerve stimulation (PENS)
The FDA regulates PENS stimulators as class II devices (Product Code NHI). Several PENS devices have been approved by the FDA. See the following website for more information and search by product name in device name section: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed October 1, 2018)

Dorsal Root Ganglion (DRG) Stimulation Devices
There are several devices used for DRG stimulation. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed October 1, 2018)

Scrambler Therapy (ST)
The Calamare/ST MC-5A TENS Device was initially approved by the FDA on February 20, 2009. A second 510(k) clearance was issued on May 22, 2015, for the ST MC-5A Device (Product Code GZJ). For more information, please go to the following websites: https://www.accessdata.fda.gov/cdrh_docs/pdf8/K081255.pdf,
https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142666.pdf. (Accessed September 28, 2018)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [*2019T0126Y*]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description

01/01/2019	• Reorganized policy template:
	  ○ Simplified and relocated *Instructions for Use*
	  ○ Removed *Benefit Considerations* section
	• Revised coverage rationale:
	  ○ Simplified content
	  ○ Modified language to clarify the listed services are:
	    ▪ Proven ***and*** medically necessary (as described)
	    ▪ Unproven ***and*** not medically necessary (as described)
	  ○ Added language to indicate scrambler therapy (ST) is unproven and not medically necessary
	• Updated list of applicable CPT codes; added 0278T and 64999
	• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references
	• Archived previous policy version DME 035.18 T2

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies 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.