

Cigna Medical Coverage Policy- Therapy Services Electric Stimulation for Pain, Swelling and Function in a Clinic Setting

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Medically Necessary

Use of electric stimulation (e.g. TENS, EMS) is considered medically necessary for an individual who has not responded to other modalities and treatments, when prescribed as part of a comprehensive treatment program for pain and swelling, and only used short term up to 2 weeks.

Note: The medical records must document a response to the use of electrical stimulation, including specific parameters related to the type of electric stimulation (e.g. low or high frequency TENS, electrode placement).

Neuromuscular Electrical Stimulation (NMES) is considered medically necessary for disuse atrophy where the nerve to the muscle is intact and the individual has any of the following non-neurological reasons for the disuse atrophy and only in conjunction with active exercise:

- Major hip or knee surgery where there is failure to respond to basic therapeutic exercises as initiated in physical therapy/rehabilitation; or

- Previous immobilization (e.g. casting or splinting) of an extremity (arm or leg)

Experimental, Investigational, Unproven

Microcurrent electrical nerve stimulation (MENS) therapy is considered experimental, investigational or unproven for the treatment of chronic back pain and all other indications

Microcurrent point stimulation is considered experimental, investigational, or unproven for the treatment of chronic pain and any other indications.

Threshold Electrical Stimulation is considered experimental, investigational, or unproven for the treatment of motor disorders, including but not limited to cerebral palsy.

H-WAVE[®] stimulation is considered experimental, investigational, or unproven for diabetic peripheral neuropathy and for all other indications including:

1. To accelerate healing; or
2. To reduce edema; or
3. To reduce pain from causes other than chronic diabetic peripheral neuropathy; or
4. To treat chronic pain due to ischemia.

Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) are considered experimental, investigational or unproven for any indication.

NMES/Electrical Stimulation (e.g. Guardian dysphagia dual chamber unit, VitalStim Therapy device) is considered experimental, investigational or unproven for the treatment of dysphagia.

Deep Pharyngeal Neuromuscular Stimulation (DPNS) is considered experimental, investigational or unproven.

Pelvic floor stimulation (electric and magnetic stimulation) is considered experimental, investigational or unproven for the treatment of urinary or fecal incontinence.

Cranial electrotherapy stimulation is considered experimental, investigational or unproven for any indication, including chronic pain.

Neufit Neubie device is considered experimental, investigational or unproven for any indication.

Electrical stimulation (except NMES) is contraindicated in areas of sensory deficits. A patient's sensory deficits (decrease or loss) do not allow them to provide the correct feedback necessary for the safe and effective application to the affected area. Electrical stimulation in other related areas without sensory deficits may be appropriate.

Note: For information on home electrical stimulation devices (electrical stimulators) please refer to Cigna Coverage Policy Electrical Stimulation Therapy and Home Devices.

DESCRIPTION

Electrical stimulation (ES) therapy involves the application of electrodes to the affected area of the body for the purpose of delivering electrical current. There are several forms of electrical current used in rehabilitation settings. Electrical stimulation is used for muscle re-education (disuse atrophy), pain relief, reduction of swelling, and healing enhancement. This CPG will focus on the use of electric stimulation for pain, swelling and function (muscle re-education/disuse atrophy) when used in the outpatient clinic setting.

GENERAL BACKGROUND

A TENS unit must be distinguished from other electrical stimulators (e.g., neuromuscular stimulators) which are used to directly stimulate muscles and/or motor nerves. Transcutaneous electrical nerve stimulation (TENS) is characterized by biphasic current and selectable parameters such as pulse rate and pulse width. TENS uses a battery-operated device that applies electrical stimulation via transmission of pulses of various configurations at the site of pain by wired electrodes that are taped to the surface of the skin. For example, conventional TENS or high frequency TENS delivers 40–150 hertz (Hz) compared to acupuncture-like TENS that delivers a low frequency at 1–10 Hz. Pulsed TENS uses low-intensity firing in high-frequency bursts at 100 HZ. Units often have preset programs with variations and modulations of frequencies and durations of pulses. TENS has been used for a number of applications. In theory, TENS stimulates sensory nerves to block pain signals; it also stimulates endorphin production to help normalize sympathetic function. TENS has been used to relieve acute or chronic pain related to musculoskeletal conditions, pain associated with active or post-trauma injury, obstetrical pain, or postoperative pain. TENS for pain control occurs via the gate theory or the endogenous opiate theory. Conventional transcutaneous electrical stimulation (TENS) is an example of the use of the gate theory to control or block pain. Low rate TENS is an example of the use of the endogenous opiate theory of pain control. TENS can also be delivered through the use of a form-fitting conductive garment (for example, a garment with conductive fibers that are separated from the individual's skin by layers of fabric). This garment is applied when a condition exists that precludes conventional TENS electrode placement.

Microcurrent Electrical Nerve Stimulation (MENS) involves the use of a device that delivers small amounts of electrical current (millionths of an amp) to help relieve pain and heal soft tissues of the body. The application of microcurrent stimulation to an injured area is proposed to realign the body's electrical current and increase the production of adenosine triphosphate, resulting in increased healing and recovery and blocking of perceived pain. The electrical current is subsensory and usually not felt. MENS differs from TENS in that it uses a significantly reduced electrical stimulation (i.e., 1,000 times less current than TENS). The goal of TENS is to block pain, while MENS acts on naturally-occurring electrical impulses to decrease pain by stimulating the healing process (Frequency Specific Microcurrent, 2014). Frequency specific microcurrent (FSM) is a type of microcurrent therapy. The microcurrent device has two separate channels that allow both the frequency and current to be set independently for each channel. FSM is proposed as a treatment option for nerve and muscle pain, shingles, and herpes (Frequency Specific Microcurrent, 2011).

The H-WAVE® electrical stimulation device generates a biphasic, exponentially decaying waveform with pulse-wide widths. Its waveform distinguishes it from TENS and other forms of electrical stimulators. H-WAVE® is classified as a powered muscle stimulator. The hypothesis that the H-WAVE® device (Electronic Waveform Lab, Inc., Huntington Beach, CA), a small-diameter fiber stimulator, is a paradigm shift of electrotherapeutic treatment of pain associated with human neuropathies and sports injuries is based on a number of its properties. The primary effect of H-WAVE® device stimulation (HWDS) is the stimulation of "red-slow-twitch" skeletal muscle fibers. The authors propose, based on the unique waveform, that the H-WAVE® device specifically and directly stimulates the small smooth muscle fibers within the lymphatic vessels ultimately leading to fluid shifts and reduced edema. The H-WAVE® device was designed to stimulate an ultra-low frequency (1-2 Hz), low tension, non-tetanic, and non-fatiguing contraction, which closely mimics voluntary or natural muscle contractions. The H-WAVE® device can stimulate small fibers due in part to its exponentially decaying waveform and constant current generator activity. The main advantage of these technologies over currently applied electrical stimulators (e.g., TENS, interferential, NMES high-volt galvanic, etc.) is that H-WAVE® small fiber contraction does not trigger an activation of the motor nerves of the large white muscle fibers or the sensory delta and C pain nerve fibers, thus eliminating the negative and painful effects of tetanic fatigue, which reduces transcapillary fluid shifts. Another proposed function of the H-WAVE® device is an anesthetic effect on pain conditions, unlike a TENS unit which in the short term activates a hypersensory overload effect (gate theory) to stop pain signals from reaching the thalamic region of the brain. When the H-WAVE® device is used at high frequency (60 Hz), it supposedly acts intrinsically on the nerve to deactivate the sodium pump within the nerve fiber, leading to a long-lasting anesthetic/analgesic effect due to an accumulative postsynaptic depression. The large pulse width theoretically enables contraction in the muscle for extended periods of time at a low fatigue rate and increases circulation, muscle relaxation, pain relief and wound healing. H-WAVE® stimulation has been used in the treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy. H-WAVE® electrical stimulation must be distinguished from the H-waves that are a component of electromyography.

Other waveforms are used for pain modulation as well, including interferential current (IFC), which is produced by two interfering alternating currents. Interferential stimulation (IFS) is characterized by 2 alternating-current sine

waves of differing medium frequencies that combine together to produce an interferential current that is also known as a beat pulse or alternating modulation frequency. One of the 2 currents is held at 4,000 Hz, and the other can be held constant or varied over a range of 4,001 to 4,100 Hz. Interferential therapy (IFT) delivers a crisscross current at 4000–4150 pulses per second, 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. Interferential currents reportedly can stimulate sensory, motor, and pain fibers. Because of the frequency, the interferential wave meets low impedance when crossing the skin to enter the underlying tissue. This deep tissue penetration can be adjusted to stimulate parasympathetic nerve fibers for increased blood flow. According to proponents, interferential stimulation differs from TENS because it allows a deeper penetration of the tissue with more comfort (compliance) and increased circulation.

High Voltage Galvanic Stimulation (HVGS) or high volt pulsed current (HVPC) is characterized by high voltage pulsed stimulation and is proposed primarily for local edema reduction through muscle pumping and polarity effect. High volt pulsed current (HVPC) is used for tissue healing and edema control based on polarity principles. Edema is comprised of negatively charged plasma proteins, which leak into the interstitial space. The theory of HVPC is that the high voltage stimulus applies an electrical potential which disperses the negatively charged proteins away from the edematous site, thereby helping to reduce edema (Cameron, 2017).

Neuromuscular electric stimulation (NMES) is the application of electrical current through electrodes on the skin to targeted muscles to elicit muscle contraction. NMES is proposed to promote neuromuscular re-education, improve motor unit recruitment, and thus to prevent or diminish muscle atrophy and is an established treatment modality for disuse atrophy when the nerve supply to the muscle is intact. NMES is typically used as a component of a comprehensive rehabilitation program. Compared to TENS, NMES delivers a stronger current with a wider pulse width. Neuromuscular electrical stimulation can be grouped into 2 categories: (i) stimulation of muscles to treat muscle atrophy due to disuse (e.g. post-surgical, immobilization), and (ii) enhancement of functional activity in neurologically impaired individuals. These devices within the second category use electrical impulses to activate paralyzed or weak muscles in precise sequence and have been utilized to provide SCI patients with the ability to walk (e.g., The Parastep I System). Neuromuscular electrical stimulation used in this manner is commonly known as functional electrical stimulation (FES).

Electric stimulated muscle contraction/neuromuscular electric stimulation (NMES) has been found to enhance muscle function gains post-surgically. Patients who have received an anterior cruciate ligament (ACL) reconstruction have demonstrated accelerated recovery and greater muscle function when NMES is used in combination with exercise; however the impact on functional outcomes is inconsistent (Cameron, 2017). Similar results were noted with knee OA patients and for other inflammatory conditions of the knee. Most research studied the use of NMES on the quadriceps muscle, however clinically NMES may be used for other joints and muscle groups (Cameron, 2017). Functional electric stimulation (FES) is proposed for use in certain neurologic populations. As an example, FES can be applied to the anterior tibialis muscle to assist in dorsiflexion during gait for patients with foot drop. Several studies support the integration of FES for patients with spinal cord injury or who have sustained a stroke for various activities. As long as the peripheral nervous system is intact, any patients with central nervous system dysfunction may benefit from FES use. In these situations, effectiveness of FES is thought to be most likely due to the direct effect of muscle strengthening in addition to increased excitability of the motor neuron pool produced by the motor level electrical stimulation (Cameron, 2017).

PENS and PNT combine the theories of electroacupuncture and TENS and the terms are often used interchangeably. PENS involves the delivery of an electrical current through the insertion of a needle below the skin at the site of pain compared to acupuncture that places needles based on energy flow. It is not the same as acupuncture. PENS is similar to TENS except that the needles are inserted one to four centimeters around or adjacent to the applicable nerve. Up to ten needs with five electrical channels may be used. PENS is generally reserved for patients who fail to obtain pain relief from TENS. PENS may also involve the application of electric stimulation to needles placed at the dermatomal levels corresponding to the painful area. PNT is a variation of PENS which was developed as a treatment for neck and back pain. This treatment involves insertion of very fine needle-like electrodes into the skin of the neck or back to stimulate nerve fibers in the deep tissues. The treatment regimen suggested by manufacturers typically consists of two to three, 30-minute sessions per week, for two to six weeks.

VitalStim® Therapy is a type of NMES that uses a mild electrical current that is intended to treat dysphagia by re-educating the muscles and improving swallowing. Guardian dysphagia dual chamber unit is proposed for use for muscle re-education by application of external stimulation for pharyngeal contraction. VitalStim® therapy was approved by the US Food and Drug Administration in 2001 for the treatment of dysphagia through the application of neuromuscular electrical stimulation to cervical swallowing muscles. To date, however, aside from the developer's own studies, there are no peer-reviewed publications supporting these claims. Deep pharyngeal neuromuscular stimulation (DPNS) is an electrical stimulation therapy for people with dysphagia. DPNS stimulates the cranial nerves by directly touching specific areas within the mouth and throat. This causes the pharyngeal and lingual muscles to contract. Over time, this is postulated to strengthen the patient's gag reflex and help to improve long-term swallowing functionality.

LITERATURE REVIEW

TENS

There are many published reports regarding the use of TENS for various types of conditions such as low back pain (LBP), myofascial and arthritic pain, sympathetically mediated pain, neurogenic pain, visceral pain, diabetic neuropathy and postsurgical pain. While randomized controlled trials (RCTs) have focused on both high and low frequency TENS, all of the currently available studies have methodological flaws that limit interpretation, including inadequate blinding, lack of reporting of drop outs, lack of reporting of stimulation variables, and lack of proper outcome measures (Johnson et al., 2015). However, it is recognized that TENS is widely accepted in the physician and therapy community as a treatment of a variety of etiologies of pain in combination with comprehensive treatment program.

According to the Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation Interventions for Low Back Pain publication (2001), TENS demonstrated no effectiveness for improvements in pain or function in subjects with chronic low back pain (LBP). Evidence was stated as good (level I). The Panel recommends that there is poor evidence to include or exclude TENS alone as an intervention for chronic LBP. According to The Cochrane Collaboration systematic review on TENS for chronic LBP (Khadiilkar et al., 2005) there is limited and inconsistent evidence to support the use of TENS as an isolated intervention for chronic LBP. In 2010, the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) published a report finding TENS ineffective for chronic low back pain (Dubinsky and Miyasaki, 2010). The results indicated that there are conflicting reports of TENS compared to sham TENS in the treatment of chronic low back pain, with two Class II studies showing benefit, but two Class I studies and another Class II study not showing benefit. Because the Class I studies are stronger evidence, TENS is established as ineffective for the treatment of chronic low back pain. Their recommendations were that TENS is not recommended for the treatment of chronic low back pain (Level A) and further research into the mechanism of action of TENS is needed, as well as more rigorous studies for determination of effectiveness. Per ACOEM guidelines, TENS for acute or sub-acute LBP or acute radicular pain syndromes is not recommended given insufficient evidence (ACOEM, 2007). In a review by Poitras and Brosseau (2008), it was determined that globally, high- and low-frequency TENS appears to have an immediate impact on pain levels in subjects with non-specific chronic LBP, with high-frequency TENS achieving better results. Studies included were of relatively poor quality and the lack of consistent parameters from study to study makes comparisons difficult. Based on this review, TENS appears to be of no benefit for long term pain or perceived disability (Poitras and Brosseau, 2008). Khadiilkar et al. (2008) updated the 2005 Cochrane Review to determine whether TENS is more effective than placebo for the management of chronic LBP. Only randomized controlled clinical trials (RCTs) comparing TENS to placebo in patients with chronic LBP were included. Four high-quality RCTs (585 patients) met the selection criteria. Clinical heterogeneity prevented the use of meta-analysis. There was conflicting evidence about whether TENS was beneficial in reducing back pain intensity and consistent evidence in two trials (410 patients) that it did not improve back-specific functional status. There was moderate evidence that work status and the use of medical services did not change with treatment. In general, patients treated with acupuncture-like TENS responded similarly to those treated with conventional TENS. However, in two of the trials, inadequate stimulation intensity was used for acupuncture-like TENS, given that muscle twitching was not induced. Adverse effects included minor skin irritation at the site of electrode placement. Authors concluded that the evidence from the small number of placebo-controlled trials does not support the use of TENS in the routine management of chronic LBP. Further research was encouraged.

The American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine (ASRA) support the use of TENS in their revised guideline recommending that "TENS should be used as a multimodal approach to pain management for patients with chronic back pain and may be used for other pain

conditions (e.g. neck and phantom limb pain)" (ASA/ASRA, 2010). A Cochrane review that identified 25 eligible RCTs was not favorable in their analysis of the literature support of TENS for various chronic pain conditions, primarily due to the quality of the available literature (Nnoaham and Kumbang, 2008). These authors found positive results for pain relief in 13 out of 22 studies that compared TENS to a placebo or other inactive control group. In studies that compared different TENS modes, seven of nine studies found no difference in pain relief between high vs. low frequency TENS. Overall, the low methodological quality and low power of the available literature did not allow the authors to make firm conclusions regarding the effectiveness of TENS for chronic pain.

In 2013, Pivec et al. studied the clinical and economic impact of TENS in patients with chronic LBP through analysis of a national database. This study evaluated patients who were given TENS compared with a matched group without TENS prior to intervention and at one-year follow-up. Patients who were treated with TENS had significantly fewer hospital and clinic visits, used less diagnostic imaging, had fewer physical therapy visits, and required less back surgery than patients receiving other treatment modalities. Jaurequi et al. (2016) conducted a systematic review and meta-analysis of the efficacy of TENS for the treatment of chronic, musculoskeletal low back pain. Thirteen studies, which included randomized controlled trials, cohort studies, and randomized crossover studies (n=267), met inclusion criteria. Follow-ups ranged from 2–24 weeks with a mean follow-up of seven week. The duration of treatment ranged from 2–24 weeks (mean 6 weeks). The overall standardized mean difference in pain from pre- to post-treatment with TENS showed a significant improvement of TENS on pain reduction. When subdivided into treatment duration, patients that were treated for less than five weeks (n=8 studies) had significant effects on pain, while those treated for more than five weeks did not. The heterogeneity among studies was substantially significant among the TENS groups. Limitations of the studies included: small patient populations; variations in treatment times, TENS frequency and length of follow-up; and conflicting outcomes. The authors noted that despite the positive results, large multi-center prospective randomized trials are needed to develop the appropriate treatment protocols for this patient population. According to the AHRQ Comparative Effectiveness publication on Non-Invasive Treatments for Low Back Pain (2016), additional evidence demonstrates that TENS is not effective versus sham TENS. Effectiveness of TENS was previously classified as insufficient and the strength of evidence remains low because of methodological limitations in the trials and imprecision. Evidence on harms associated with TENS was limited, but suggests an increased risk of skin site irritation without an increased risk of serious adverse events (AHRQ, 2016). According to the American College of Physician's Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain clinical practice guideline (2017), evidence was insufficient to determine the effectiveness of transcutaneous electrical nerve stimulation (TENS).

Two practice guidelines support the use of TENS, one for rheumatoid arthritis based on positive results in one (1) RCT (Ottawa Panel Evidence-Based Clinical Practice Guidelines, 2004), and one for the treatment of knee osteoarthritis based on meta-analysis of five (5) RCTs included in the analysis (Philadelphia Panel Practice Guidelines, 2001). Johnson et al. (2015) assessed the analgesic effectiveness of TENS, as a sole treatment, for acute pain in adults. Only RCTs of adults with acute pain (< 12 weeks) were examined with TENS given as a sole treatment and assessed pain was with subjective pain scales. The types of acute pain included in this Cochrane Review were procedural pain, e.g. cervical laser treatment, venipuncture, screening flexible sigmoidoscopy and non-procedural pain, e.g. postpartum uterine contractions and rib fractures. There was a high risk of bias associated with inadequate sample sizes in treatment arms and unsuccessful blinding of treatment interventions. Seven trials reported minor adverse effects, such as mild erythema and itching underneath the electrodes and participants disliking TENS sensation. Authors concluded that this review offers tentative evidence that TENS reduces pain intensity over and above that seen with placebo (no current) TENS when administered as a stand-alone treatment for acute pain in adults. The high risk of bias associated with inadequate sample sizes in treatment arms and unsuccessful blinding of treatment interventions makes definitive conclusions impossible.

Jin et al. (2010) conducted a systematic review to evaluate the effectiveness of TENS on diabetic peripheral neuropathy. Three randomized controlled trials (n=78) met inclusion criteria. TENS was reported more effective than placebo in the reduction of mean pain score at four and six weeks follow-up but not at 12 weeks. Pieber et al. (2010) conducted a systematic review of the literature to evaluate electrotherapy, including TENS, for the treatment of peripheral neuropathy in patients with diabetes. Three randomized controlled trials (n=76) and one retrospective review (n=54) evaluating TENS met inclusion criteria. The studies included short-term follow-ups and conflicting results. One study reported significant improvement in pain and another study reporting recurrence of pain after cessation of TENS. Due to the small patient populations, short-term treatment duration, short-term follow-up and poor study methodology, large multi-center randomized controlled trials are needed to further

evaluate the long-term effect of TENS on diabetic neuropathy. Hurlow et al. (2012) conducted an update review of the 2009 review by Robb et al. One new study met inclusion criteria (n=24). There were significant differences in participants, treatments, procedures and symptom measurement tools used in the studies. The clinical utility of TENS for the treatment of cancer pain has not been established. Robb et al. (2009) conducted a systematic review of the literature to evaluate TENS for the treatment of cancer-related pain. Two randomized controlled trials (n=64) met inclusion criteria. Meta-analysis was not conducted due to the disparities between patient population, mode of TENS, treatment duration, and outcome measures prevented meta-analysis. There is insufficient evidence to support TENS for the treatment of cancer-related pain.

Mulvey et al. (2010) conducted a systematic review of randomized controlled trials to assess the effectiveness of TENS for the treatment of phantom pain and stump pain following amputation in adults. No studies were identified. Johnson et al. (2015b) conducted an update of this Cochrane review and found no new randomized controlled trials evaluating TENS for the treatment of phantom pain and stump pain. Rheumatoid Arthritis: In a systematic review of the literature, Brosseau et al. (2003) evaluated the effectiveness of TENS for the treatment of rheumatoid arthritis of the hand. Three randomized controlled trials (n=78) met inclusion criteria. Conventional TENS (C-TENS) and acupuncture-TENS (acu-TENS) were compared to either placebo or each other. Pain outcomes on the effect of TENS were conflicting. Acu-TENS was beneficial for reducing pain intensity and improving muscle power scores compared to placebo. No clinical benefit on pain was reported with C-TENS compared to placebo. C-TENS resulted in a clinical benefit on the patients' assessment of change compared to acu-TENS. The authors concluded that more well designed studies with a standardized protocol and adequate numbers of subjects were needed to fully identify the effect of TENS for the treatment of RA of the hand.

Dissanayaka et al. (2016) compared the effectiveness of transcutaneous electrical nerve stimulation and interferential therapy (IFT) both in combination with hot pack, myofascial release, active range of motion exercise, and a home exercise program on myofascial pain syndrome patients with upper trapezius myofascial trigger point. Following randomization of patients into three groups (hot pack, active range of motion exercises, myofascial release, and a home exercise program with postural advice), transcutaneous electrical nerve stimulation-standard care and IFT-standard care-were administered eight 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 transcutaneous electrical nerve stimulation 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 (P < 0.05). The IFT group showed significant improvement on these outcome measurements than the control group did (P < 0.05). Authors concluded that TENS with standard care facilitates recovery better than IFT does in the same combination.

Page et al. (2016) completed a Cochrane Database Systematic Review on electrotherapy modalities for rotator cuff disease. Examples included therapeutic ultrasound, low-level laser therapy (LLLT), transcutaneous electrical nerve stimulation (TENS), and pulsed electromagnetic field therapy (PEMF). These modalities are usually delivered as components of a physical therapy intervention. Authors synthesized the available evidence regarding the benefits and harms of electrotherapy modalities for the treatment of people with rotator cuff disease. Randomized controlled trials (RCTs) and quasi-randomized trials, including adults with rotator cuff disease (e.g. subacromial impingement syndrome, rotator cuff tendinitis, calcific tendinitis), and comparing any electrotherapy modality with placebo, no intervention, a different electrotherapy modality or any other intervention (e.g. glucocorticoid injection) were included. Trials investigating whether electrotherapy modalities were more effective than placebo or no treatment, or were an effective addition to another physical therapy intervention (e.g. manual therapy or exercise) were the main comparisons of interest. Main outcomes of interest were overall pain, function, pain on motion, patient-reported global assessment of treatment success, quality of life and the number of participants experiencing adverse events. Most trials (n = 43) included participants with rotator cuff disease without calcification (four trials included people with calcific tendinitis). Sixteen (34%) trials investigated the effect of an electrotherapy modality delivered in isolation. Only 23% were rated at low risk of allocation bias, and 49% were rated at low risk of both performance and detection bias (for self-reported outcomes). The trials were heterogeneous in terms of population, intervention and comparator, so none of the data could be combined in a meta-analysis. Authors were uncertain whether transcutaneous electrical nerve stimulation (TENS) was more or less effective than glucocorticoid injection with respect to pain, function, global treatment success and active range of motion because of the very low quality evidence from a single trial. Authors concluded that uncertainty exists as to whether TENS is superior to placebo, and whether any electrotherapy modality provides benefits over other

active interventions (e.g. glucocorticoid injection) because of the very low quality of the evidence. Further trials of electrotherapy modalities for rotator cuff disease should be based upon a strong rationale and consideration of whether or not they would alter the conclusions of this review.

In an article by Vance et al. (2014) titled “Using TENS for pain control: the state of the evidence,” Transcutaneous electrical nerve stimulation (TENS) is described as a nonpharmacological intervention that activates a complex neuronal network to reduce pain by activating descending inhibitory systems in the central nervous system to reduce hyperalgesia. Within the article, authors describe the current mechanisms of TENS reduction on analgesia, which is thought to be more complex than previously described. More specifically, TENS activates a complex neuronal network to result in a reduction in pain. At frequencies and intensities used clinically, TENS activates large diameter afferent fibers. This afferent input is sent to the central nervous system to activate descending inhibitory systems to reduce hyperalgesia. Specifically, blockade of neuronal activity in the periaqueductal gray (PAG), rostral ventromedial medulla (RVM) and spinal cord inhibit the analgesic effects of TENS showing that TENS analgesia is maintained through these pathways. In parallel, studies in people with fibromyalgia show that TENS can restore central pain modulation, a measure of central inhibition. Therefore, TENS appears to reduce hyperalgesia through both peripheral and central mechanisms. Authors do report that the evidence for TENS efficacy is conflicting. Sluka et al. (2013) suggests that certain factors should be considered when evaluating the research. These include dosing of TENS, negative interactions with long-term opioid use, the population and outcome assessed, timing of outcome measurement, and comparison groups. Population-specific systemic reviews and meta-analyses are emerging, indicating both high frequency (HF) and low frequency (LF) TENS being shown to provide analgesia, specifically when applied at a strong, non-painful intensity. They conclude that additional research is necessary to determine if TENS has effects specific to mechanical stimuli and/or beyond reduction of pain and will improve activity levels, function and quality of life. These authors are considered experts in the area of TENS research and they offer these interesting practice points:

- High frequency (HF) and low frequency (LF) transcutaneous electrical nerve stimulation (TENS) activate different opioid receptors. Both applications have been shown to provide analgesia specifically when applied at a strong, non-painful intensity. HF TENS may be more effective for people taking opioids.
- Effective analgesia for chronic pain conditions may be limited by the development of tolerance to TENS if repeated application of either LF or HF TENS at the same frequency and intensity is used daily (i.e., same dose). Strategies to prolong analgesia may include varying these parameters.
- Targeting the use of TENS during movement or activity may be most beneficial.
- TENS may be effective in restoration of central pain modulation, a measure of central inhibition.
- A clearer picture of TENS effectiveness will emerge as trials with attention to optimal dosing and appropriate outcome measures increase in numbers.

Gibson et al. (2019) provided an overview of evidence from Cochrane Reviews of the effectiveness of TENS to reduce pain in adults with chronic pain (excluding headache or migraine). They included nine reviews investigating TENS use in people with defined chronic pain or in people with chronic conditions associated with ongoing pain. The evidence reported within each review was consistently rated as very low quality. since we would predict these different comparisons may be estimating different true effects. Authors found the methodological quality of the reviews was good, but quality of the evidence within them was very low. They were therefore unable to conclude with any confidence that, in people with chronic pain, TENS is harmful, or beneficial for pain control, disability, health-related quality of life, use of pain-relieving medicines, or global impression of change. Pietrosimone et al. (2020) aimed to determine the effect of TENS + therapeutic exercise (TE) on patient-reported function, quadriceps strength, and voluntary activation, as well as physical performance compared with sham TENS + TE (Sham) and TE alone in individuals with symptomatic knee OA and quadriceps voluntary activation failure (QVAF). Ninety individuals participated in a double-blinded randomized controlled trial. Everyone received 10 standardized TE sessions of physical therapy. TENS + TE and Sham groups applied the respective devices during all TE sessions and throughout activities of daily living over 4 wk. Improvements in WOMAC subscales, quadriceps strength, and voluntary activation, 20-m walk times, chair-stand repetitions, and stair-climb time were found at post 1 and post 2 compared with baseline for all groups ($P < 0.05$). WOMAC Pain and Stiffness improved in the TENS + TE group compared with TE alone at post 1 ($P < 0.05$); yet, no other between-group differences were found. Authors concluded that TE effectively improved patient-reported function, quadriceps strength, and voluntary activation, as well as physical performance in individuals with symptomatic KOA and QVAF, but augmenting TE with TENS did not improve the benefits of TE.

A Best Practices for Chiropractic Management of Patients with Chronic Musculoskeletal Pain: A Clinical Practice Guideline authored by Hawk et al. (2020), for chronic low back pain, TENS or interferential current may be beneficial as part of a multimodal approach, at the beginning of treatment to assist the patient in becoming or remaining active. For chronic neck pain, they recommend TENS and interferential current in the same manner as for chronic low back pain.

Microcurrent Electrical Nerve Stimulation

There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and effectiveness of MENS including frequency specific microcurrent (FSM). Studies include small patient populations and short-term follow-ups with conflicting outcomes and in some cases reported outcomes were no better than placebo (Rajpurohit et al., 2010; Zuim et al., 2006). More recently, microcurrent, using very small electrical devices contained within wound dressings, has been evaluated as a therapy to speed the closure of chronic wounds. However, research published to date has not produced findings that suggest this form of ES can accelerate wound closure (Houghton, 2014). Nair (2018) did not see some positive findings for wound healing, however more research is needed to confirm results.

H-WAVE®

There is insufficient evidence in the published peer reviewed scientific literature to support the safety and effectiveness of the H-WAVE® electrical stimulators. Blum et al. (2008) conducted a systematic review and meta-analysis of randomized and nonrandomized controlled trials to evaluate the safety and efficacy of H-WAVE® therapy. Five studies (n=6535) met inclusion criteria. H-WAVE® was shown to decrease pain across various chronic soft tissue inflammation and neuropathic pain conditions, decrease pain medication intake (n=2 studies) and increase functionality (n=2 studies). However, author-noted limitations of the studies included the heterogeneity of the studies, inconsistency of the effects (e.g., reduction in pain medication, functionality), data were obtained from cross-sectional studies, data were subjective in nature (i.e., there were no formal examination findings, test results and/or laboratory values), various outcome measures, potential selection bias of publications for this review, and due to a lack of reported data it was not possible to statistically evaluate the safety of the therapy.

Threshold Electrical Stimulation (TES)

Dali et al. (2002) sought to determine whether a group of stable children with cerebral palsy would improve their motor skills after 12 months of TES. Two thirds received active and one third received inactive stimulators. Fifty seven of 82 outpatients who were able to walk at least with a walker, completed all 12 months of treatment. Results demonstrated that there was no significant difference between active and placebo treatment in any of the tested groups, nor combined. Authors concluded that TES in these patients did not have any significant clinical effect during the test period. Kerr et al. (2006) investigated the efficacy of NMES and TES in strengthening the quadriceps muscles of both legs in children with cerebral palsy (CP). Sixty children were randomized to one of the following groups: NMES (n=18), TES (n=20), or placebo (n=22). Thirty-four children walked unaided, 17 used posterior walkers, six used crutches, and the remaining three used sticks for mobility. Peak torque of the left and right quadriceps muscles, gross motor function, and impact of disability were assessed at baseline and end of treatment (16wks), and at a 6-week follow-up visit. No statistically significant difference was demonstrated between NMES or TES versus placebo for strength or function. Statistically significant differences were observed between NMES and TES versus placebo for impact of disability at the end of treatment, but only between TES and placebo at the 6-week follow-up. In conclusion, further evidence is required to show whether NMES and/or TES may be useful as an adjunct to therapy in ambulatory children with diplegia who find resistive strengthening programmes difficult.

Interferential Current (IFC)

Studies for IFC are primarily in the form of case reports, case series and some randomized controlled trials with small patient populations, short-term treatment sessions and short-term follow-ups. Randomized controlled trials with large patient populations and long-term follow-ups comparing IFT to established treatment options are lacking. The California Technology Assessment Forum (2005) evaluated the literature on IFT for the treatment of musculoskeletal pain and concluded that this treatment modality has not been shown to be as beneficial as alternative treatments such as nonsteroidal anti-inflammatory drugs and exercise therapy. Although IFT was found to be a generally safe technique, it did not meet the CTAF technology assessment criteria for the treatment of musculoskeletal pain. Fuentes et al. (2010) conducted a systematic review and meta-analysis of randomized controlled trials (n=20) to evaluate the pain-reducing effectiveness of IFC in the management of musculoskeletal

pain. Twenty studies met inclusion criteria. Seven studies assessed IFC for joint pain (e.g., osteoarthritis), nine for muscle pain (e.g., low back pain, neck pain), three for soft tissue shoulder pain (e.g., tendinitis) and one for postoperative pain. Three studies were considered to be of poor methodological quality, 14 of moderate quality and three of high quality. Methodological issues included small sample sizes, heterogeneity of patient population, inappropriate handling of withdrawals and dropouts, and lack of appropriate randomization, concealment of allocation and blinding of patients and assessors. Fourteen studies (n=1114) were used for meta-analysis. Only three studies reported adverse events (e.g., blisters, burns, bruising, swelling). The authors concluded that the analgesic effect that IFC is superior to that of the concomitant interventions was unknown; IFC alone was not significantly better than placebo or other therapy at discharge or follow-up; the heterogeneity across studies and methodological limitations prevented conclusive statements regarding analgesic efficacy; and the results should be viewed with caution due to the limited number of studies that used IFC as a monotherapy. The American College of Physicians and the American Pain Society Joint Clinical Practice Guideline for the Diagnosis and Treatment of LBP (Chou and Huffman 2007) concluded that there was not enough evidence to support the use of interferential therapy, TENS, traction, ultrasound, or short wave diathermy for acute or chronic LBP. These results were based on systematic reviews and randomized trials of one or more of the aforementioned therapies for treatment of acute or chronic LBP that reported pain outcomes, back specific function, general health status, work disability or patient satisfaction. In a review by Poitras and Brosseau (2008), they determined that due to limited studies of sufficient quality, no recommendations could be made for the use of ultrasound, interferential current, or electrical muscle stimulation for the treatment of chronic LBP. Facci et al. (2011) compared the effects of TENS and interferential current among patients with nonspecific chronic low back pain. One hundred and fifty patients were randomly divided into three groups: TENS (group 1), interferential current (group 2) and controls (group 3). The patients designated for electrotherapy received ten 30-minute sessions, while the control group remained untreated. All patients and controls were evaluated before and after treatment using a visual analog scale and the McGill Pain and Roland Morris questionnaires, and regarding their use of additional medications. Results showed no statistically significant difference between the TENS and interferential current groups. The only difference was found between these groups and the controls, with noted improvement in outcome measures for the treatment groups. According to the AHRQ publication on Non-Invasive Treatments for Low Back Pain (2016), insufficient evidence from four trials exists regarding the effectiveness of interferential therapy versus other interventions, or interferential therapy plus another intervention versus the other interventions alone for low back pain, due to methodological limitations and imprecision. According to the American College of Physician's Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain clinical practice guideline (2017), evidence was insufficient to determine the effectiveness of electrical muscle stimulation and inferential therapy.

Rutjes et al. (2009) conducted a systematic review of randomized or quasi-randomized controlled trials of electrical stimulation, including IFT (n=4 studies), for the treatment of osteoarthritis of the knee. Due to the poor methodological and reporting quality of the studies, the effectiveness of IFT could not be confirmed. Zeng et al. (2015) investigated the efficacy of different electrical stimulation (ES) therapies in pain relief of patients with knee osteoarthritis (OA). 27 trials and six kinds of ES therapies, including high-frequency transcutaneous electrical nerve stimulation (h-TENS), low-frequency transcutaneous electrical nerve stimulation (l-TENS), neuromuscular electrical stimulation (NMES), interferential current (IFC), pulsed electrical stimulation (PES), and noninvasive interactive neurostimulation (NIN), were included. IFC was the only significantly effective treatment in terms of both pain intensity and change pain score at last follow-up time point when compared with the control group. Meanwhile, IFC showed the greatest probability of being the best option among the six treatment methods in pain relief. However, the evidence of heterogeneity and the limitation in sample size of some studies could be a potential threat to the validity of results. Authors also state that although the recommendation level of the other ES therapies is either uncertain (h-TENS) or not appropriate (l-TENS, NMES, PES and NIN) for pain relief, it is likely that none of the interventions is dangerous. Almeida et al. (2018) investigated the effects of transcutaneous electrical nerve stimulation and interferential current on acute and chronic pain. Eight studies with a pooled sample of 825 patients were included. In general, both transcutaneous electrical nerve stimulation and interferential current improved pain and functional outcomes without a statistical difference between them. Authors concluded that transcutaneous electrical nerve stimulation and interferential current have similar effects on pain outcome. The low number of studies included in this meta-analysis indicates that new clinical trials are needed.

Kadi et al. (2019) evaluated IFS for treating pain after total knee arthroplasty surgery. A total of 113 individuals were randomized to IFS (n=57) or sham treatment (n=56). There were 98 individuals (87%) who completed the study. After 30 days, there was no significant difference between groups in pain assessed by a VAS, 0.278. Pain medication use (paracetamol) also did not differ significantly between groups after treatment and neither did

outcome measures assessing range of motion or edema. In this study, IFS was not beneficial at improving outcomes after total knee arthroplasty.

High Volt Galvanic Stimulation (HVGS)

The few studies identified in the literature addressing HVGS were mostly randomized clinical trials and case studies published before 1997 with small patient populations and short-term follow-up. Patient selection criteria were lacking. More recently, Snyder et al. (2010) systematically reviewed the basic-science literature regarding the effects of high-voltage pulsed stimulation (HVPS) for edema control. Included studies investigated HVPS and its effect on acute edema formation and included outcome measures specific to edema. Eleven studies met the inclusion criteria. Studies were critiqued by electrical stimulation treatment parameters: mode of stimulation, polarity, frequency, duration of treatment, voltage, intensity, number of treatments, and overall time of treatments. According to Snyder et al., (2010), the available evidence indicates that HVPS administered using negative polarity, pulse frequency of 120 pulses/s, and intensity of 90% visual motor contraction may be effective at curbing edema formation. In addition, according to authors, evidence suggests that treatment should be administered in either four 30-min treatment sessions (30-min treatment, 30-min rest cycle for 4 h) or a single, continuous 180-min session to achieve the edema-suppressing effects. Often such treatment occurs in an athletic training room for college athletes and may not be feasible in an outpatient clinical setting. Authors suggest that findings supported by the basic science research provides a general list of treatment parameters that may successfully manage the formation of edema after acute injury in animal subjects. They believe this should facilitate further research related to HVPS and the effects on edema in humans. At this time, there is insufficient evidence in the published peer reviewed scientific literature to support the safety and efficacy of HVG/HVPS stimulation.

PENS and PNT

There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of PENS or PNT as a treatment option for chronic pain. Overall, studies have included small patient populations and short term follow-ups. For low back pain, most of the literature is of poor quality with all trials evaluating chronic low back pain. In a technology brief, Hayes (2017) investigated the effectiveness of PENS for the treatment of low back pain (LBP). Three randomized controlled trials (n=34 to 200) evaluated the efficacy and safety of PENS for chronic LBP (CLBP) in adults and one study evaluated PNT for subacute radiating LBP. Hayes rated the studies as very low-quality of evidence. There was no clinically significant improvement with the use of PENS. When compared with other therapies, PENS monotherapy was favored over treatment with PENS followed by TENS or TENS alone at one month; however, the difference was not maintained at two months. Another study reported no difference in outcomes with PENS vs. sham. There is insufficient evidence to support PENS for the treatment of LBP. Weiner et al. (2008) conducted a randomized controlled trial (n=200) to evaluate the efficacy of PENS in adults with chronic low back pain. Patients were randomized to either 1) PENS, 2) brief electrical stimulation to control for treatment expectance (control-PENS), 3) PENS plus general conditioning and aerobic exercise (GCAE) or to 4) control-PENS plus GCAE. Treatment was delivered twice a week for six weeks to the 50 participants in each group. All groups reported significantly reduced pain (McGill Pain Questionnaire short form) and disability and improved gait velocity, which was sustained at six months. Significantly fewer fear avoidance beliefs were reported in the CGAE group compared to the non-CGAE group. Comparable reduced pain and function were reported by the PENS and control-PENS group, whether delivered for five minutes or 30 minutes. Thus, the exact dose of electrical stimulation needed for analgesia could not be determined. PENS and GCAE were more effective than PENS alone in reducing fear avoidance beliefs, but not in reducing pain or in improving physical function. There was a statistically significant improvement in chair rise time in the control-PENS plus CGAE compared to control-PENS alone. The overall drop-out rate was 8%. In the Agency for Healthcare Research and Quality (AHRQ) publication "Noninvasive Treatments for Low Back Pain" by Chou et al. (2016), the two studies on PENS that were of fair quality contradicted one another, as one found that PENS plus exercise was superior to sham plus exercise, while the other did not. Some studies looked at LBP with radicular signs while others did not or were unclear. Overall, the literature doesn't support PENS for treatment of chronic low back pain without radicular symptoms. There was insufficient evidence to determine effects of PENS versus sham, PENS plus exercise versus exercise alone, or PENS versus other interventions (TENS), due to methodological limitations and imprecision. Harms were poorly reported in trials of PENS.

Kang et al. (2007) conducted a single-blinded, randomized study of 63 patients with knee pain secondary to osteoarthritis. Twenty-eight patients were randomly assigned to the sham group and 35 to the live treatment group. The study investigated the efficacy of PNT in reducing knee pain and medication consumption during the first week following treatment. Pain levels were rated on a 100-mm visual analog pain scale. The live group had greater

efficacy than the sham group in all time periods; however, only in the immediate post-treatment period did it reach statistical significance ($p=0.0361$). The overall median pain intensity difference over all periods was 14.5 for the live group and 6.5 for the sham group and reached statistical significance. At one week follow-up, the live group reported significantly less medication use than the sham group. Plaza-Manzano et al. (2020) evaluated the effects of percutaneous electrical stimulation (PENS) alone or as an adjunct with other interventions on pain and related disability in musculoskeletal pain conditions. Sixteen studies were included and included heterogeneous musculoskeletal conditions with short- or midterm follow-ups. The risk of bias was generally low; but the heterogeneity of the results downgraded the level of evidence. Authors concluded that there is low level of evidence suggesting the effects of PENS alone or in combination for pain, but not related disability, in musculoskeletal pain.

NMES and FES

Electric stimulated muscle contraction/neuromuscular electric stimulation (NMES) has been found to enhance muscle function post surgically. Patients who have received an ACL reconstruction have demonstrated accelerated recovery and greater muscle function when NMES is used in combination with exercise; however the impact on functional outcomes is inconsistent (Cameron, 2017). Similar results were noted with knee OA patients and for other inflammatory conditions of the knee. Most research studied the use of NMES on the quadriceps muscle, however clinically NMES may be used for other joints and muscle groups (Cameron, 2017). NMES has been shown to be part of an effective rehabilitative regimen for patients following ligament/knee surgery. It may help prevent muscle atrophy associated with knee immobilization, may enable patients to ambulate sooner, and may reduce the use of pain medication as well as length of hospital stay (Arvidsson, 1986; Lake, 1992; Gotlin et al, 1994; Snyder-Mackler et al, 1991 and 1995). Bax et al (2005) systematically reviewed the available evidence for the use of NMES in increasing strength of the quadriceps femoris. The authors concluded that limited evidence suggests that NMES can improve strength in comparison with no exercise, but volitional exercises appear more effective in most situations. The authors' cautious conclusions reflect the general poor quality of the included studies. It is also important to understand that at the time NMES is used, it is to re-education the neuromuscular system and engage more motor units with muscle contraction. Given this, the mechanism of strength increase is likely due to improved neuromuscular action vs. a true strength increase of the muscle.

Monaghan et al. (2010) completed a Cochrane review regarding the effectiveness of NMES as a means of increasing quadriceps strength in patients before and after total knee replacement. Only two studies were identified for inclusion in the review. No significant differences were reported in either study for maximum voluntary isometric torque or endurance between the NMES group and the control group but significantly better quadriceps muscle activation was reported in the exercise and neuromuscular stimulation group compared with the exercise group alone in the second study. This difference was significant at the mid training (six week) time point but not at the twelfth week post training time point. Both studies carried a high risk of bias. Mean values were not given for strength, endurance, cross sectional area or quality of life. Pain outcomes, patient satisfaction or adverse effects were not reported in either study. The results were presented as percentage improvements from baseline and the number of subjects in each group was unclear. Authors concluded that the studies found in this review do not permit any conclusions to be made about the application of neuromuscular stimulation for the purposes of quadriceps strengthening before or after total knee replacement. At that time the evidence for the use of neuromuscular stimulation for the purposes of quadriceps strengthening in this patient group is unclear.

Kim et al. (2010) performed a systematic review of RCTs assessing the effects of NMES on quadriceps strength, functional performance, and self-reported function after ACL reconstruction. Eight randomized controlled trials were included. Authors concluded that NMES combined with exercise may be more effective in improving quadriceps strength than exercise alone, whereas its effect on functional performance and patient-oriented outcomes is inconclusive. Inconsistencies were noted in the NMES parameters and application of NMES. Imoto et al. (2011) systematically evaluated the effectiveness of electrical stimulation on rehabilitation after ligament and meniscal injuries. Seventeen studies evaluating ES after anterior cruciate ligament reconstruction and two studies evaluating ES after meniscectomy were included. There was a statistically significant improvement in quadriceps strength through ES and in functional outcomes six to eight weeks after surgical reconstruction of the anterior cruciate ligament. Authors concluded that there is evidence that ES coupled with conventional rehabilitation exercises may be effective in improving muscle strength and function two months after surgery. Maddocks et al. (2013) evaluated the effectiveness of NMES for improving muscle strength in adults with advanced disease and to examine the acceptability and safety of NMES, and changes in muscle function (strength or endurance), muscle mass, exercise capacity, breathlessness and health-related quality of life. They included randomized controlled trials (RCTs) in adults with advanced chronic obstructive pulmonary disease (COPD), chronic heart failure, cancer

or human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) comparing a program of NMES as a sole or adjunct intervention to no treatment, placebo NMES or an active control. Eleven studies involving a total of 218 participants met the inclusion criteria across COPD, chronic heart failure and thoracic cancer. Authors concluded NMES appears an effective means of improving muscle weakness in adults with progressive diseases such as COPD, chronic heart failure and cancer. Further research is needed to confirm findings and determine most effective parameters.

Bemner et al. (2016) completed a critically appraised topic on the effectiveness of neuromuscular electrical stimulation in improving voluntary activation of the quadriceps. Four randomized controlled trials (RCTs) met the inclusion criteria and were included. Of the included studies, one reported statistically significant improvements in quadriceps voluntary activation in the intervention group relative to a comparison group, but the statistical significance was not true for another study consisting of the same sample of participants with a different follow-up period. One study reported a trend in the NMES group, but the between group differences were not statistically significant in three of the four RCTs. Current evidence does not support the use of NMES for the purpose of enhancing quadriceps voluntary activation in patients with orthopedic knee conditions. There is level B evidence that the use of NMES alone, or in conjunction with therapeutic exercise, does not enhance quadriceps voluntary activation in patients with orthopedic knee conditions (e.g., anterior cruciate ligament injuries, osteoarthritis, total knee arthroplasty).

Jones et al. (2016) updated a Cochrane Database review on the effectiveness of neuromuscular electrical stimulation for quadriceps muscle weakness in adults with advanced disease. Programs of NMES appear to be acceptable to patients and have led to improvements in muscle function, exercise capacity, and quality of life. However, estimates regarding the effectiveness of NMES based on individual studies lack power and precision. Randomized controlled trials in adults with advanced chronic respiratory disease, chronic heart failure, cancer, or HIV/AIDS comparing a program of NMES as a sole or adjunct intervention to no treatment placebo NMES, or an active control were included. Eighteen studies (20 reports) involving a total of 933 participants with COPD, chronic respiratory disease, chronic heart failure, and/or thoracic cancer met the inclusion criteria for this update, an additional seven studies since the previous version of this review. All but one study that compared NMES to resistance training compared a program of NMES to no treatment or placebo NMES. Most studies were conducted in a single center and had a risk of bias arising from a lack of participant or assessor blinding and small study size. The quality of the evidence using GRADE comparing NMES to control was low for quadriceps muscle strength, moderate for occurrence of adverse events, and very low to low for all other secondary outcomes. The included studies reported no serious adverse events and a low incidence of muscle soreness following NMES. NMES led to a statistically significant improvement in quadriceps muscle strength. An increase in muscle mass was also observed following NMES, though the observable effect appeared dependent on the assessment modality used. Across tests of exercise performance, mean differences compared to control were statistically significant for the 6-minute walk, but not for the incremental shuttle walk, endurance shuttle walk, or for cardiopulmonary exercise testing with cycle ergometry. Authors concluded that NMES may be an effective treatment for muscle weakness in adults with advanced progressive disease, and could be considered as an exercise treatment for use within rehabilitation programs. Further research is very likely to have an important impact on the confidence in the estimate of effect and may change the estimate. Further research to understand the role of NMES as a component of, and in relation to, existing rehabilitation approaches is needed. Gatewood et al. (2017) aimed to investigate the efficacy of device modalities used following arthroscopic knee surgery. Outcome measures included: muscle strength, range of motion, swelling, blood loss, pain relief, narcotic use, knee function evaluation and scores, patient satisfaction and length of hospital stay. Twenty-five studies were included in this systematic review, nineteen of which found a significant difference in outcomes. Authors concluded that NMES improve quadriceps strength and overall knee functional outcomes following knee surgery. Yue et al. (2018) assessed the evidence relative to the comparative effectiveness of neuromuscular electrical stimulation (NMES), transcutaneous electrical nerve stimulation (TENS), and electroacupuncture (EA) for improving patient rehabilitation following total knee arthroplasty (TKA). Data were analyzed from 17 randomized controlled trials involving 1285 procedures: 8 NMES studies (608 procedures), 7 TENS studies (560 procedures), and 2 EA studies (117 procedures). Qualitative analysis suggested that NMES was associated with higher quadriceps strength and functional recovery after TKA. Recovery benefits were maximal when the stimulation was performed once or twice a day for 4-6 weeks at an intensity of 100-120 mA and frequency of 30-100 Hz. The electrode should be sufficiently large (100-200 cm²) to reduce discomfort. TENS at an intensity of 15-40 mA and frequency of 70-150 Hz provided effective analgesia after TKA. EA at an intensity of 2 mA and frequency of 2 Hz may also provide postoperative analgesia of TKA. Authors concluded that as adjunct modalities, NMES and TENS can effectively improve rehabilitation after TKA without triggering significant intolerance, and maximal benefits depend on optimized parameters and

intervention protocols. EA may be an effective adjunct modality for analgesia after TKA. Novak et al. (2020) sought to provide guidelines for treatment parameters regarding electrical stimulation by investigating its efficacy in improving muscle strength and decreasing pain in patients with knee osteoarthritis. Nine randomized control trials were included in the review. First, the review confirmed that neuromuscular electrical stimulation is the most effective electrical stimulation treatment in the management of knee OA, and its efficiency is higher when combined with a strengthening program. Second, frequency of at least 50 Hz and no more than 75 Hz with a pulse duration between 200 and 400 μ s and a treatment duration of 20 mins is necessary for successful treatment.

The main goal of stroke rehabilitation is to improve function to allow patients greater independence in their activities of daily living, resulting in an improvement in quality of life. Typical treatment techniques of stroke rehabilitation comprise various combination of range of motion (ROM) and muscle strengthening exercises, mobilization activities, and compensatory techniques. Other key therapies include neurophysiological and/or developmental based methods in which the treatment program incorporates neuromuscular re-education techniques. It is in these situations that FES is used for stroke rehabilitation. It has been utilized to manage contracture of joints, maintain ROM, facilitate voluntary motor control, and reduce spasticity. However, there is insufficient evidence that FES is effective as a rehabilitative tool for patients who suffered strokes. In particular, there are little data supporting the long-term effectiveness of this modality for stroke rehabilitation and other neurologic conditions. In a Cochrane review, Price and Pandyan (2000) ascertained the effectiveness of any form of surface electric stimulation in the prevention and/or treatment of pain around the shoulder at any time after stroke. These investigators concluded that the evidence from randomized controlled studies so far does not confirm or refute that ES around the shoulder after stroke influences reports of pain, but there do appear to be benefits for passive humeral lateral rotation. A possible mechanism is through the reduction of glenohumeral subluxation. The authors stated that further studies are needed. Van Peppen et al (2004) determined the evidence for physical therapy interventions aimed at improving functional outcome after stroke. 151 studies were included in this systematic review; 123 were randomized controlled trials (RCTs) and 28 controlled clinical trials (CCTs). Researchers reported that while strong evidence was found regarding use of NMES for glenohumeral subluxation, no or insufficient evidence in terms of functional outcome was found for FES and NMES aimed at improving dexterity or gait performance. Furthermore, in a review on therapeutic orthosis and electric stimulation for upper extremity hemiplegia after stroke, Aoyagi and Tsubahara (2004) stated that despite a number of studies suggesting the effectiveness of electrical stimulation for reducing shoulder subluxation or improving the function of wrist and finger extensors in the short term, the long term effectiveness after discontinuation as well as the motor recovery mechanism remains unclear. More research is needed to determine the evidence-based effectiveness of electrical stimulation for stroke survivors. Koyuncu et al. (2010) conducted a randomized controlled trial to evaluate FES for the treatment of 50 hemiplegic patients with shoulder subluxation and pain secondary to stroke. All patients received conventional rehabilitation and the study group also received FES stimulation to the supraspinatus and posterior deltoid muscles on the hemiplegic side, five times a day, one hour each for four weeks. Comparison of the resting AROM vs. PROM VAS value changes showed no significant difference between the groups. There was a significant difference between the two groups for the amount of change in shoulder subluxation in favor of the study group, indicating increased stability of the shoulder. Authors suggest that that applying FES treatment to the supraspinatus and posterior deltoid muscles in addition to conventional treatment when treating the subluxation in hemiplegic patients is more beneficial than conventional treatment by itself. Gu and Ran (2016) reviewed the evidence for the effect of functional electrical stimulation (FES) on shoulder subluxation, pain, upper arm motor function, daily function, and quality of life in patients with stroke when added to conventional therapy. The results of this meta-analysis showed a significant difference in shoulder subluxation between the FES group and the placebo group, only if FES was applied early after stroke. And a significant difference was observed posttreatment in the Fugl-Meyer Motor Assessment between the FES group and the placebo group. No effects were found on pain, upper arm motor function, daily function, and quality of life outcomes. Authors concluded that FES can be used to prevent or reduce shoulder subluxation early after stroke. However, findings did not support the efficacy of use of FES for pain reduction, improvement in arm strength, movement, functional use, daily function, or quality of life after stroke.

FES has been proposed for improving ambulation in patients with gait disorders such as drop foot, hemiplegia due to stroke, cerebral injury, or incomplete spinal cord injury. As an example, FES can be applied to the anterior tibialis muscle to assist in dorsiflexion during gait for patients with foot drop. Several small studies support the integration of FES for patients with spinal cord injury or who have sustained a stroke for various activities. As long as the peripheral nervous system is intact, any patients with central nervous system dysfunction may benefit from FES use. Effectiveness of FES may be likely due to the direct effect of muscle strengthening in addition to increased excitability of the motor neuron pool produced by the motor level electrical stimulation (Cameron, 2017).

Yan and colleagues (2005) evaluated whether FES was more effective in promoting motor recovery of the lower extremity and walking ability than standard rehabilitation alone. A total of 46 patients were assigned randomly to one of three groups receiving standard rehabilitation with FES or placebo stimulation or alone (control). They received treatment for 3 weeks, starting shortly after having the stroke. Outcome measurements included composite spasticity score, maximum isometric voluntary contraction of ankle dorsi-flexors and planter-flexors, and walking ability. After 3 weeks of treatment, those receiving FES plus standard rehabilitation did better on several measures of lower limb functioning compared to the other 2 groups. All patients in the FES group were able to walk after treatment, and 84.6 % of them returned home, in comparison with the placebo (53.3 %) and control (46.2 %) groups. However, these authors stated that generalization of the results from this study should be performed with caution because of subject selection criteria, which did not cover all stroke categories or subjects aged younger than 45 or older than 85 years. Randomized controlled trials and case series have primarily included small patient populations (n=14-64) with short-term follow-ups and heterogeneous treatment regimens and outcome measures (Esnour, et al., 2010; Nooijen, et al., 2009; Everaert, et al., 2010; Stein, et al., 2010; Barrett, et al., 2010; Postans, et al., 2004).

In a Cochrane review on electrostimulation for promoting recovery of movement or functional ability after stroke, Pomeroy et al (2006) sought to find out whether electrostimulation improved functional motor ability to do activities of daily living. Twenty-four trials were included in the review. Authors reported that electrostimulation improved some aspects of functional motor ability and some aspects of motor impairment and normality of movement over no treatment. For electrostimulation compared with placebo, this review found that electrostimulation improved an aspect of functional motor ability. For electrostimulation compared with conventional physical therapy, they found that electrostimulation improved an aspect of motor impairment. There were no statistically significant differences between electrostimulation and control treatment for all other outcomes. Authors caution that these results need to be interpreted with reference to the following: (1) the majority of analyses only contained one trial; (2) variation was found between included trials in time after stroke, level of functional deficit, and dose of electrostimulation; and (3) the possibility of selection and detection bias in the majority of included trials. Researchers conclude that data were insufficient to inform clinical use of electrostimulation for neuromuscular re-training. Research is needed to address specific questions about the type of electrostimulation that might be most effective, in what dose and at what time after stroke. Pereira et al. (2012) conducted a systematic review of randomized controlled trials to evaluate the effectiveness of FES in improving lower limb function in chronic stroke patients (mean time since stroke \geq 6 mos). Seven RCTs including a pooled sample size of 231 participants met inclusion criteria. Analysis revealed a small but significant treatment effect in favor of FES on the 6 minute walk test. Authors conclude that FES may be an effective intervention in the chronic phase post stroke. However, its therapeutic value in improving lower extremity function and advantage over other gait training approaches remains uncertain.

More recently, Howlett et al. (2015) conducted a systematic review and meta-analysis to investigate the effectiveness of FES in improving activity following a stroke and to determine if FES is more effective than training alone. Eighteen randomized and non-randomized comparisons studies (n=485) met inclusion criteria. One study had three arms which was counted as a separate comparison group (n=19 comparisons). Because of incomplete data, all trials were not included in the meta-analysis. Only measures that reflected the International Classification of Function domain of activity performance were used in analyses. In some trials only one measure was available and in trials with more than one measure the reviewers chose the measure that most closely reflected the task being trained. Various outcome measures were used for lower-limb and upper-limb activity assessments. FES had a small to moderate effect on activity compared to no FES or placebo and had a moderate effect on activity compared to training alone. However, due to the lack of available data, the authors were unable to determine if FES improved subject participation or if the benefits of FES are long-term. Author-noted limitations of the studies included: the lack of blinding of therapist and participants; the potential of small trial bias with 25 being the average number of participants per trial; and combining data for the meta-analysis that was collected using different outcome measures. There was also heterogeneity of subject characteristics including time after stroke, the limb that was trained, and the severity of stroke. In a randomized controlled study, Bethoux et al. (2015) compared changes in gait quality and function between FES and ankle-foot orthoses (AFOs) in individuals with foot drop post-stroke over a 12 month period. They completed a follow-up analysis on a multi-center unblinded RCT that had been conducted at 30 rehabilitation centers. Subjects continued to wear their randomized device for all home and community ambulation for another 6 months to final 12-month assessments. Primary outcomes were the 10 Meter Walk Test (10MWT) and device-related serious adverse event rate. Secondary outcome measures were the 6-Minute Walk Test (6MWT), GaitRite Functional Ambulation Profile, and the Modified Emory Functional Ambulation Profile (mEFAP). A total of 495 subjects were randomized, and 384 completed the 12-month follow-up. Both FES and AFO groups showed statistically and clinically significant improvement for 10MWT. No

significant between group differences were found. At 12 months, both FES and AFOs continue to demonstrate equivalent gains in gait speed. Results suggest that long-term FES use may lead to additional improvements in walking endurance and functional ambulation; further research is needed to confirm these findings.

Prenton et al. (2016) conducted a systematic review and meta-analysis of randomized controlled trials to compare the effects of FES and ankle foot orthoses (AFO) for foot drop of central neurological origin. Five synthesized randomized controlled trials (n=815) were included. Orthotics included customized and off the shelf AFOs. Meta-analysis of the outcomes of the 10-meter (m) walking speed (5 trials) (n=789) and functional exercise capacity (3 trials) (n=761) showed between group comparable improvements which were not significant ($p=0.79$; $p=0.31$, respectively). There were no significant differences in meta-analysis for the 10-meter (m) walk test using data at short- (4 trials; n=771) and longer-term (3 trials; n=713) time-points for FES vs. AFO. There was a significant difference ($p=0.04$) in favor of the AFO for the medium-term 10-m test. Analyses revealed between group comparable improvements in functional exercise capacity. The timed up-and-go test was reported in two studies and both reported between-group comparable improvements ($p=0.812$ and $p=0.539$). The mobility domain of the Stroke Impact Scale (SIS) was reported by three trials (n=701) and showed comparable between-group improvements ($p=0.80$). This meta-analysis indicates that AFOs have positive combined-orthotic effects on walking that are equivalent to FES for foot-drop caused by stroke regardless of length of use. The fact that the reviewed trials only included subjects age 18 years and older who had experienced a stroke prevents the results from being generalized to other populations. Other limitations of the analysis included the risk of bias in the studies and the heterogeneity of the AFO and FES devices used.

Stein et al. (2015) conducted a systematic review (n=29 studies; 940 subjects) and meta-analysis (n=14 studies; 383 subjects) of randomized controlled trials to evaluate the effect of NMES on spastic muscles after stroke. The primary outcome was spasticity, assessed by the Modified Ashworth Scale. The secondary outcome was range of motion (n=13 studies), assessed by a goniometer. Outcomes were conflicting. Some studies reported an improvement in spasticity (n=12 studies) and range of motion (n=13 studies) with NMES when used as an adjunctive therapy and some studies did not. Based on sensitivity analysis, no effects on spasticity and range of motion were seen on wrists and no effect on spasticity of elbows. The degree of spasticity and the criteria for spasticity assessment varied. Most studies showed evidence of bias. Other study limitations included: heterogeneity of outcome measures; time of treatment following stroke (1.5 months to more than 12 months); various degrees of chronic tissue changes; heterogeneity of conventional therapies used (e.g., active leg cycling, occupational therapy, stretching, Botulinum Toxin A), missing data; and heterogeneity of stimulation frequency and pulse duration. Large scale and high-quality randomized controlled trials are needed to establish the true efficacy NMES in this patient population. Sharififar et al. (2018) aimed to determine the effect on motor function of extremities of adding an electrical sensory modality without motor recruitment before or with routine rehabilitation for hemiparesis after stroke by a comprehensive systematic review and meta-analysis. Authors concluded that electrical sensory input can contribute to routine rehabilitation to improve early post-stroke lower-extremity impairment and late motor function, with no change in spasticity. Prolonged periods of sensory stimulation such as TENS combined with activity can have beneficial effects on impairment and function after stroke.

Chiu et al. (2014) conducted a systematic review to determine the effectiveness of FES vs. activity training alone in children with cerebral palsy. Five randomized controlled trials met inclusion criteria. The experimental group had to receive FES while performing an activity such as walking. The studies used outcome measures of activity that best reflected the activity used in the study. When continuous data (e.g., walking speed) were not available, ordinal data (e.g., Gross Motor Function Measurement) were used. A statistically significant between-group difference in activity in the FES groups was reported for the three studies that compared FES with no FES. Improvements were seen immediately after the intervention period, but long-term follow-up was not reported. The two 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. Outcomes could not be pooled for meta-analysis due to incomplete data and the large difference in baseline scores. Due to the inability to conduct a meta-analysis, the authors stated that firm conclusions could not be made. Limitations of the studies included the heterogeneous patient populations and the variations in the frequency, intensity and duration of the interventions. Bosques et al. (2016) discussed the potential clinical applicability, while clarifying the differences in electrical stimulation (ES) treatments and the theory behind potential benefits to remediate functional impairments in youth in a comprehensive review. The synthesis of the literature suggests that improvements in various impairments may be possible with the integration of ES. Most studies were completed on children with cerebral palsy (CP). Electrical stimulation may improve muscle mass and strength,

spasticity, passive range of motion (PROM), upper extremity function, walking speed, and positioning of the foot and ankle kinematics during walking. Sitting posture and static/dynamic sitting balance may be improved with ES to trunk musculature. Bone mineral density may be positively affected with the use of Functional Electrical Stimulation (FES) ergometry. ES may also be useful in the management of urinary tract dysfunction and chronic constipation. Among all reviewed studies, reports of direct adverse reactions to electrical stimulation were rare. In conclusion, NMES and FES appear to be safe and well tolerated in children with various disabilities. Authors suggested that physiatrists and other healthcare providers better understand the indications and parameters in order to utilize these tools effectively in the pediatric population.

Springer and Khamis (2017) completed a systematic review on the orthotic and therapeutic effects of functional electrical stimulation on gait in people with multiple sclerosis (MS). Twelve relevant studies were reviewed. Eleven studies reported the effects of peroneal stimulation. Most found a significant orthotic effect (measured during stimulation), mainly on walking speed. Only three assessed the therapeutic effect (carry-over), which was not significant. Authors concluded that the evidence suggests that FES has a positive orthotic effect on walking in patients with MS. Yet, more robust trials are needed to substantiate this finding. Therapeutic efficacy of FES was not demonstrated,

Electrical stimulation (ES) has been examined for the treatment of dysphagia. However, there is currently insufficient evidence to support the effectiveness of ES in treating this condition. No peer-reviewed literature was found for DPNS specifically, but rather is limited to electrical stimulation, FES, or NMES. In a non-concurrent cohort study, Blumenfeld et al. (2006) assessed the effectiveness of ES in treating persons with dysphagia and aspiration. The charts of 40 consecutive subjects undergoing ES and 40 consecutive persons undergoing traditional dysphagia therapy (TDT) were reviewed. The swallow severity scale improved from 0.50 to 1.48 in the TDT group ($p < 0.05$) and from 0.28 to 3.23 in the ES group ($p < 0.001$). After adjusting for potential confounding factors, persons receiving ES did significantly better in regard to improvement in their swallowing function than persons receiving TDT ($p = 0.003$). The authors concluded that the findings suggested that dysphagia therapy with transcutaneous ES is superior to traditional dysphagia therapy alone in individuals in a long-term acute care facility. They also stated that confirmation of these findings with a prospective, placebo-controlled, randomized clinical trial is needed before a definitive determination regarding the effectiveness of ES dysphagia therapy can be made. Kiger et al. (2006) compared the outcomes using transcutaneous neuromuscular electrical stimulation (VitalStim® therapy) to outcomes using traditional swallowing therapy for deglutition disorders. A total of 22 patients had an initial and a follow-up video-fluoroscopic swallowing study or fiberoptic endoscopic evaluation of swallowing and were divided into an experimental group that received VitalStim® treatments and a control group that received traditional swallowing therapy. Outcomes were analyzed for changes in oral and pharyngeal phase dysphagia severity, dietary consistency restrictions, and progression from non-oral to oral intake. Results of chi-square analysis showed no statistically significant difference in outcomes between the experimental and control groups. Huckabee and Doeltgen (2007) reviewed NMES as an emerging modality in an attempt to advise the New Zealand medical community about the application of it as a treatment for pharyngeal swallowing impairment (dysphagia). Authors conclude that there are potential benefits of the use of this treatment but key concerns for patient safety and long term outcomes exist. Shaw et al. (2007) sought to evaluate the effectiveness of VitalStim® therapy in a heterogeneous group of dysphagic patients. They performed a retrospective analysis of 18 patients who received this therapy at an urban tertiary referral center. All patients underwent pre-therapy evaluation by speech-language pathologists, including modified barium swallow and/or functional endoscopic evaluation of swallowing and clinical evaluation of swallowing that included assessment of laryngeal elevation, diet tolerance, and swallowing delay, and were then assigned an overall dysphagia severity score. After therapy, all patients underwent the same assessments. Twelve of the 18 also underwent a functional swallowing telephone survey months (range, 1 to 21 months) after their therapy to assess whether the improvement was worthwhile and sustained. Eleven of the 18 patients (61%) demonstrated some improvement in their swallowing. Six of the 18 patients (33%) were improved enough to no longer require a feeding tube. However, of the 5 patients categorized as having "severe dysphagia" before therapy, only 2 showed any improvement, and these patients still required a feeding tube for adequate nutrition. Telephone surveys did confirm that those who improved with their therapy seemed to maintain their progress and that most patients were satisfied with their therapy. Authors concluded that VitalStim therapy seems to help those with mild to moderate dysphagia. However, the patients with the most severe dysphagia in the study did not gain independence from their feeding tubes but could potential help those with mild to moderate dysphagia. Carnaby-Mann and Crary (2007) examined the evidence on neuromuscular electrical stimulation for swallowing rehabilitation. A total of 81 studies were reviewed. Seven were accepted for analysis. A significant summary effect size was identified for the application of NMES for swallowing. Best-evidence synthesis showed indicative findings in favor of NMES for swallowing. The analysis revealed a small but

significant summary effect size for NMES for swallowing. Because of the small number of studies and low methodological grading for these studies, caution should be taken in interpreting this finding. These results support the need for more rigorous research in this area. This is in agreement with the observation of Steel et al (2007) who noted that although ES approaches to the restoration and rehabilitation of swallowing is an exciting area of research which holds promise for future clinically relevant technology and/or therapy, implementation of ES in clinical swallowing rehabilitation settings still remains pre-mature.

Clark et al. (2009) systematically reviewed the literature examining the effects of NMES on swallowing and neural activation. The review was conducted as part of a series examining the effects of oral motor exercises (OMEs) on speech, swallowing, and neural activation. Out of 899 citations initially identified for the broad review of OMEs, 14 articles relating to NMES qualified for inclusion. Most of the studies (10/14) were considered exploratory research, and many had significant methodological limitations. Authors concluded that the review revealed that surface NMES to the neck has been most extensively studied with promising findings, yet high-quality controlled trials are needed to provide evidence of efficacy. Surface NMES to the palate, faucial pillars, and pharynx has been explored in Phase I research, but no evidence of efficacy is currently available. Intramuscular NMES has been investigated in a single Phase I exploratory study. Additional research is needed to document the effects of such protocols on swallowing performance. Christiaanse et al. (2011) compared the change in swallowing function in pediatric patients with dysphagia who received neuromuscular electrical stimulation (NMES) to a control group who received usual oral motor training and dietary manipulations without NMES. Children were classified into two groups based on the etiology of their dysphagia (primary vs. acquired). Only the treatment group who had acquired dysphagia improved more than the similar subgroup of control children. Authors concluded that NMES treatment of anterior neck muscles in a heterogeneous group of pediatric patients with dysphagia did not improve the swallow function more than that seen in patients who did not receive NMES treatment. However, there may be subgroups of children that will improve with NMES treatment. Geeganage et al. (2012) assessed the effectiveness of interventions for the treatment of dysphagia and nutritional and fluid supplementation in patients with acute and subacute stroke. Authors included 33 studies involving 6779 participants. Swallowing therapies included the following: acupuncture, drug therapy, neuromuscular electrical stimulation, pharyngeal electrical stimulation, physical stimulation (thermal, tactile), transcranial direct current stimulation, and transcranial magnetic stimulation. Authors conclude that there remains insufficient data on the effect of swallowing therapy, feeding, and nutritional and fluid supplementation on functional outcome and death in dysphagic patients with acute or subacute stroke. Behavioural interventions and acupuncture reduced dysphagia, and pharyngeal electrical stimulation reduced pharyngeal transit time.

Tan et al. (2013) assessed the overall efficacy by comparing the two treatment protocols in a meta-analysis. Studies that compared the efficacy of treatment and clinical outcomes of NMES versus traditional treatment (TT) in dysphagia rehabilitation were assessed. Seven studies were eligible for inclusion, including 291 patients, 175 of whom received NMES and 116 of whom received TT. Of the seven studies, there were two randomized controlled trials, one multicentre randomized controlled trial and four clinical controlled trials. The change scores on the Swallowing Function Scale of patients with dysphagia treated with NMES were significantly higher compared with patients treated with TT. However, subgroup analysis according to etiology showed that there were no differences between NMES and TT in dysphagia post-stroke. No studies reported complications of NMES. Authors concluded that NMES is more effective for treatment of adult dysphagia patients of variable etiologies than TT. However, in patients with dysphagia post-stroke, the effectiveness was comparable. Miller et al (2014) performed a systematic review of the literature on the use of neuromuscular electrostimulation (NMES) in otorhinolaryngology that have been published in German or English. The search identified 180 studies. These were evaluated and relevant studies were included in the further evaluation. The authors concluded that the evidence collected to date is encouraging; particularly for the treatment of certain forms of dysphagia and laryngeal paresis. Terré and Mearin (2015) evaluated the effectiveness of neuromuscular electrical stimulation (NMES) treatment in patients with oropharyngeal dysphagia secondary to acquired brain injury. Twenty patients with neurological oropharyngeal dysphagia (14 stroke and six severe traumatic brain injury) were enrolled in a prospective randomized study, with patients and assessors blinded (to group allocation): 10 patients underwent NMES and conventional swallowing therapy and 10 patients underwent sham electrical stimulation (SES) and conventional swallowing therapy. Both groups completed 20 sessions. Feeding swallowing capacity was evaluated using the functional oral intake scale (FOIS). After treatment, the NMES group increased by 2.6 points (4.5 points) compared with only 1 point (3.1 points) for the SES group. At 3 months of follow-up, mean scores were 5.3 and 4.6 respectively; thus, both groups improved similarly. At that time point (3 months), tracheal aspiration persisted in six patients in each group. However, a significant improvement in relation to the bolus viscosity at which aspiration appeared was found in the NMES group versus the SES group. Also, a significant

increase in pharyngeal amplitude contraction was observed at the end of treatment (1 month) in the NMES group compared with the SES group. Authors concluded that NMES significantly accelerated swallowing function improvement in patients with oropharyngeal dysphagia secondary to acquired brain injury. Chen et al. (2016) evaluated whether swallow treatment with neuromuscular electrical stimulation is superior to that without neuromuscular electrical stimulation, and whether neuromuscular electrical stimulation alone is superior to swallow therapy. Eight studies were identified. Authors concluded that swallow treatment with neuromuscular electrical stimulation seems to be more effective than that without neuromuscular electrical stimulation for post-stroke dysphagia in the short term considering the limited number of studies available. Evidence was insufficient to indicate that neuromuscular electrical stimulation alone was superior to swallow therapy. Alamer et al. (2020) summarized the latest best scientific evidence on the efficacy of neuromuscular electrical stimulation on swallowing function in dysphagic stroke patients. Evidence of overall quality was graded from moderate to high. Eleven RCTs involving 784 patients were analyzed. The primary outcome measures of this review were functional dysphagia scale (FDS) and standard swallowing assessment. This review found neuromuscular electrical stimulation (NMES) coupled with traditional swallowing therapy could be an optional intervention to improve swallowing function after stroke in rehabilitation department.

Literature does not support the use of NMES for the treatment of heart failure (Arena et al., 2010) conducted a systematic review of the literature to evaluate the evidence supporting NMES and inspiratory muscle training (IMT) for the treatment of systolic heart failure. Thirteen NMES studies met inclusion criteria, ten were randomized controlled trials. Although the studies reported improvement in aerobic capacity, peak oxygen uptake and strength and endurance of muscle groups, the studies were limited by patient population (i.e., mostly males), diverse NMES training protocols, variation in the type of muscle contraction elicited (i.e., titanic vs. twitch), the use of different muscle groups and different comparators. The percent improvement in peak oxygen uptake was consistently greater with conventional therapy (i.e., bicycle/treadmill). Sillen et al. (2009) conducted a systematic review of randomized controlled trials to analyze the role of NMES in strength, exercise capacity, and disease-specific health status in patients with congestive heart failure (n=9 studies) and chronic obstructive pulmonary disease (n=5 studies) with disabling dyspnea, fatigue, and exercise intolerance. The limited number of studies, heterogeneous patient populations and variability in NMES methodology prohibited the use of meta-analysis. Although some of the studies reported significant improvements with NMES compared to no exercise or usual care, outcomes, including adverse events, were conflicting. Additional studies are indicated to provide sufficient evidence to establish the clinical utility of NMES in this patient population.

Pelvic Floor Stimulation (electric or electromagnetic)

Stewart et al. (2017) assessed the effects of electrical stimulation with non-implanted devices, alone or in combination with other treatment, for managing stress urinary incontinence or stress-predominant mixed urinary incontinence in women. Eligible trials (n=56) included adult women with SUI or stress-predominant mixed urinary incontinence (MUI). Authors concluded that electrical stimulation (ES) probably improves incontinence-specific quality of life (QoL) compared to no treatment but there may be little or no difference between electrical stimulation and pelvic floor muscle training (PFMT). Consistent with other reviews, it is uncertain whether adding electrical stimulation to PFMT makes any difference in terms of quality of life, compared with PFMT alone. The impact of electrical stimulation on subjective cure/improvement and incontinence-specific QoL, compared with vaginal cones, PFMT plus vaginal cones, or drug therapy, is uncertain. Comparisons of different types of ES to each other and of ES plus surgery to surgery are also inconclusive in terms of subjective cure/improvement and incontinence-specific QoL. Authors concluded that the current evidence base indicated that electrical stimulation is probably more effective than no active or sham treatment, but it is not possible to say whether ES is similar to PFMT or other active treatments in effectiveness or not. Overall, the quality of the evidence was too low to provide reliable results. Pan et al. (2018) evaluated the value of magnetic stimulation (MS) in patients with pelvic floor dysfunction (PFD). A total of 20 studies including 1019 patients were eligible for inclusion whose level of evidence for the included studies was low. Meta-analysis of four trials comparing MS with sham intervention showed that MS was not associated with significant improvement in outcomes or QoL, or number of leakages. Narrative review showed that there were no convincing evidences that MS was effective for chronic pelvic floor pain, detrusor overactivity, or overactive bladder. Authors concluded that there is no convincing evidence to support the benefits of using MS in the management of PFD. The applicability of MS in the treatment of PFD remains uncertain, so larger, well-designed trials with longer follow-up periods adopted relevant and comparable outcomes are needed to be further explored to provide a definitive conclusion.

Cranial Electrotherapy Stimulation

O'Connell et al. (2018) evaluated the efficacy of non-invasive cortical stimulation techniques in the treatment of chronic pain. Non-invasive brain stimulation techniques aim to induce an electrical stimulation of the brain in an attempt to reduce chronic pain by directly altering brain activity. They include repetitive transcranial magnetic stimulation (rTMS), cranial electrotherapy stimulation (CES), transcranial direct current stimulation (tDCS), transcranial random noise stimulation (tRNS) and reduced impedance non-invasive cortical electrostimulation (RINCE). Outcomes of interest were pain intensity measured using visual analogue scales or numerical rating scales, disability, quality of life and adverse events. A total of 94 trials were included in this review (involving 2983 randomised participants). Authors concluded that there is very low-quality evidence that single doses of high-frequency rTMS of the motor cortex and tDCS may have short-term effects on chronic pain and quality of life but multiple sources of bias exist that may have influenced the observed effects. They did not find evidence that low-frequency rTMS, rTMS applied to the dorsolateral prefrontal cortex and CES are effective for reducing pain intensity in chronic pain. There remains a need for substantially larger, rigorously designed studies.

Neufit Neubie device

There is a paucity of published literature to support the use of the Neufit Neubie device for electrical stimulation and therefore conclusions about the safety and efficacy of the device or combination units cannot be made.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®*	Description
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to one or more areas; electrical stimulation (manual) each 15 minutes

HCPCS Codes	Description
G0283	Electrical stimulation unattended, to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

*Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.

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