


DME- Electrical Stimulation for Pain PENS -TENS UNIT AHM

Clinical Indications

- **Transcutaneous electrical nerve stimulators (TENS)** is considered medically necessary durable medical equipment (DME) when **1 or more** of the following criteria is met: [\[A\]](#)
 - When used as an adjunct to the use of drugs either in the treatment of acute post-operative pain in the first 30 days after surgery
 - For certain types of chronic, intractable pain not adequately responsive to other methods of treatment including, as appropriate, physical therapy and pharmacotherapy.
 - When TENS is used for acute post-operative or chronic intractable pain and has completed a 1-month trial period, [\[B\]](#) continued TENS treatment may be considered medically necessary if physician documents that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time.
- Note: When TENS is used for acute post-operative or chronic intractable pain, use of the device is considered medically necessary initially for a trial period of at least 1 month but not to exceed 2 months. The trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain. After this 1-month trial period, continued TENS treatment may be considered medically necessary if the treatment significantly alleviates pain and if the attending physician documents that the patient is likely to derive significant therapeutic benefit from continuous use of the unit over a long period of time. The physician's records must document a reevaluation of the member at the end of the trial period, must indicate how often the member used the TENS unit, the typical duration of use each time, and the results.
- Form-fitting conductive garment medically necessary DME only when it has been approved for marketing by the FDA, has been prescribed by a doctor for delivering TENS for one of the medically necessary indications listed above, and **1 or more** of the following criteria is met:
 - The member can not manage without the conductive garment due to the large area or the large number of sites to be stimulated, and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires
 - The member has a medical need for rehabilitation strengthening following an injury where the nerve supply to the muscle is intact

- The member has a skin problem or other medical conditions that precludes the application of conventional electrodes, adhesive tapes, and lead wires
- The member requires electrical stimulation beneath a cast to treat disuse atrophy, where the nerve supply to the muscle is intact.
- **Percutaneous electrical nerve stimulation (PENS)** (also known as percutaneous neuromodulation) is considered medically necessary DME for (i) up to a 30-day period for the treatment of members with chronic low back pain secondary to degenerative disc disease when PENS is used as part of a multi-modality rehabilitation program that includes **ALL** of the following
 - Exercise
 - The treatment of members with diabetic neuropathy or neuropathic pain who failed to adequately respond to conventional treatments including **3 or more** of the following groups of agents:
 - anti-convulsants (e.g., pregabalin)
 - anti-depressants (e.g., amitriptyline, and duloxetine)
 - opioids (e.g., morphine sulphate and tramadol)
 - other pharmacological agents (e.g., capsaicin and isosorbide dinitrate spray).
- Peripherally implanted nerve stimulators are considered medically necessary DME for treatment of members with intractable neurogenic pain when **ALL** of the following criteria are met:
 - Member has chronic intractable pain, refractory to other methods of treatment (e.g., analgesics, physical therapy, local injection, surgery)
 - Member is not addicted to drugs (per American Society of Addiction Medicine guidelines)
 - There is no psychological contraindication to peripheral nerve stimulation,
 - There is objective evidence of pathology (e.g., electromyography)
 - Trial of transcutaneous stimulation was successful (resulting in at least a 50 % reduction in pain).

Indications considered Not Medically Necessary

- FES of the upper extremities (e.g., NESS H200) is considered investigational for all indications, including improvement of muscle strength, reduction of spasticity and atrophy, and facilitation of functional motor movement due to any of the following conditions
 - Spinal cord injury
 - Stroke (cerebrovascular accident/CVA)
 - Traumatic brain injury
 - Other upper motor neuron disorders (e.g., Parkinson's disease)
- FES  and NMES is considered investigational for all other indications, including any of the following:
 - Bell's palsy
 - Cerebral palsy
 - For cardiac conditioning
 - For general muscle strengthening in healthy individuals
 - For improving ambulatory function and muscle strength for progressive diseases (e.g., cancer, chronic heart failure, chronic obstructive pulmonary disease, multiple sclerosis) in persons without spinal cord injury
 - For the treatment of denervated muscles
 - For the treatment of knee osteoarthritis
- Electrical stimulation of the sacral anterior roots in conjunction with posterior rhizotomy (Vocare Blader System) is considered investigational for all other indications
- Transurethral electrical stimulation is considered investigational for the management of neurogenic bladder dysfunction and all other indications because its effectiveness for these indications has not been established

- Peroneal nerve stimulator (e.g., the WalkAide device, the Bioness, and the NESS L300 Foot Drop System) is considered investigational for persons with foot drop and for all other indications because of insufficient evidence to support its use for these indications
- Threshold (or therapeutic) electrical stimulation is considered investigational for the management of cerebral palsy and other motor disorders because its effectiveness for these indications has not been established.
- TENS is considered experimental and investigational for acute pain (less than 3 months duration) other than post-operative pain.
- TENS is also considered experimental and investigational for acute and chronic headaches, chronic low back pain, deep abdominal pain, hip fracture pain, neuropathic pain, pelvic pain, temporomandibular joint (TMJ) pain and all other indications because there is inadequate scientific evidence to support its efficacy for these specific types of pain.
- **PENS** is considered experimental and investigational for the treatment of chronic neck pain and all other indications because its effectiveness for these indications has not been established.
- Peripheral nerve stimulation is considered experimental and investigational for post-herpetic neuralgia and all other indications because its effectiveness for these indications has not been established.
- H-WAVE type stimulators are considered experimental and investigational for diabetic peripheral neuropathy and for all other indications including **1 or more** of the following indications because their effectiveness for these indications has not been established.
 - To accelerate healing
 - To reduce edema
 - To reduce pain from causes other than chronic diabetic peripheral neuropathy
 - To treat chronic pain due to ischemia

Evidence Summary

- **Background**
- A TENS is a device which utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins. 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 is characterized by biphasic current and selectable parameters such as pulse rate and pulse width. In theory, TENS stimulates sensory nerves to block pain signals; it also stimulates endorphin production to help normalize sympathetic function. Most TENS units produce current of 1 to 80 microampere (mA), 9 V (average), 2 to 1000 Hz, with a pulse width of 250 to 400 microseconds (mS).
- Transcutaneous electrical nerve stimulation has been widely used in the treatment of various types of pain. It has been shown that TENS is highly effective in alleviating pain and reducing analgesic medications following cesarean section, orthopedic and thoracic operations as well as mixed surgical procedures (AHCPR, 1992). Moreover, TENS has been found to be beneficial also to those who suffer from acute musculoskeletal pain (Long, 1991). On the other hand, the use of TENS in the treatment of chronic malignant pain is sparse and its effectiveness remains unproven. Studies by Ventafridda and colleagues (1979) reported that of the 159 cancer patients who experienced short-term pain relief with TENS therapy, 58 % of them found the treatment ineffective by day 10, and only 35 % of these subjects continued its use after 1 month. In another group of 37 patients, pain was markedly reduced in 96 % of them during the first 10 days of TENS treatment.
- However, pain reduction was found only in 33 % of the subjects during the second 10 days, and to only 11 % during the third 10 days. Physical mobility was improved initially in 76 % of patients, but dropped to 19 % by the end of 1 month (Ventafridda et al, 1979). The Canadian Coordinating

Office for Health Technology Assessment evaluated the clinical value of TENS in pain management and concluded that there is little evidence of the effectiveness of TENS in treating chronic pain (1995).

- On June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) rendered a decision memo for TENS for chronic low back pain. It states that TENS is not reasonable and necessary for the treatment of chronic low back pain. The CMS will only cover TENS if individuals are enrolled in an approved clinical study meeting specific requirements.
- The Centers for Medicare & Medicaid Services (2012) has issued a decision memorandum concluding that TENS not reasonable and necessary for the treatment of chronic low back pain. For purposes of the decision memorandum, chronic low back pain was defined as an episode of low back pain that has persisted for three months or longer; and is not a manifestation of a clearly defined and generally recognizable primary disease entity. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain systemic diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus.
- The CMS decision memorandum stated that the evidence demonstrates that the use of TENS for chronic low back pain as defined within the scope of this analysis does not produce a clinically meaningful improvement in any of the considered health outcomes. The decision memorandum stated that it is apparent that sham (placebo) TENS produces equivalent analgesia as active TENS.
- In an evidence-based review, the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology evaluated the effectiveness of TENS in the treatment of pain in neurological disorders (Dubinsky and Miyasaki, 2010). There are conflicting reports of TENS compared to sham TENS in the treatment of chronic low back pain (LBP), with 2 Class II studies showing benefit, while 2 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 LBP. On the other hand, TENS is probably effective in treating painful diabetic neuropathy (2 Class II studies).
- The authors concluded that (i) TENS is not recommended for the treatment of chronic LBP (Level A), and (ii) TENS should be considered in the treatment of painful diabetic neuropathy (Level B). They stated that further research into the mechanism of action of TENS is needed, as well as more rigorous studies for determination of efficacy.
- Guidelines on treatment of LBP from the National Collaborating Centre for Primary Care (Savigny et al, 2009) found insufficient evidence for the use of TENS in LBP and recommended against its use for that indication.
- In a Cochrane review, Mulvey et al (2010) evaluated the analgesic effectiveness of TENS for the treatment of phantom pain and stump pain following amputation in adults. These investigators searched MEDLINE, Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, PsycINFO, AMED, CINAHL, PEDRO and SPORTDiscus (February 2010). Only randomized controlled trials (RCTs) investigating the use of TENS for the management of phantom pain and stump pain following an amputation in adults were included. Two review authors independently assessed trial quality and extracted data. It was planned that where available and appropriate, data from outcome measures were to be pooled and presented as an overall estimate of the effectiveness of TENS. No RCTs that examined the effectiveness of TENS for the treatment of phantom pain and stump pain in adults were identified by the searches.
- The authors concluded that there were no RCTs on which to judge the effectiveness of TENS for the management of phantom pain and stump pain. The published literature on TENS for phantom pain and stump pain lacks the methodological rigor and robust reporting needed to confidently assess its effectiveness. They stated that further RCT evidence is needed before such a judgment can be made.
- Cheing and Luk (2005) examined the clinical effectiveness of high-frequency (HF) TENS for reducing hyper-sensitivity of the hand in patients with neuropathic pain. A total of 19 patients suffering from hand hyper-sensitivity were randomly assigned into either a treatment or a placebo

group. A visual analog scale (VAS) and the Downey Hand Center Hand Sensitivity Test were used to measure the tactile tolerance of the hand. Grip strength was assessed by a grip dynamometer. Daily applications of electrical stimulation were provided for 2 weeks. Significantly lower pain scores were found in the treatment group than in the placebo group by day 7 and day 11. The ranking of 10 dowel textures of the Downey Hand Center Hand Sensitivity Test in the treatment group was significantly higher than in the placebo group by day 7 and day 11. However, no significant inter-group difference was found in grip strength.

- The Ad hoc Committee of the Croatian Society for Neurovascular Disorders and the Croatian Medical Association's recommendations for neuropathic pain treatment (Demarin et al, 2008) stated that damage to the somatosensory nervous system poses a risk for the development of neuropathic pain. Such an injury to the nervous system results in a series of neurobiological events resulting in sensitization of both the peripheral and central nervous system. The diagnosis of neuropathic pain is based primarily on the history and physical examination finding. Although monotherapy is the ideal approach, rational poly-pharmacy is often pragmatically used. Several classes of drugs are moderately effective, but complete or near-complete relief is unlikely. Anti-depressants and anti-convulsants are most commonly used. Opioid analgesics can provide some relief but are less effective than for nociceptive pain; adverse effects may prevent adequate analgesia.
- Topical drugs and a lidocaine-containing patch may be effective for peripheral syndromes. Sympathetic blockade is usually ineffective except for some patients with complex regional pain syndrome. TENS was not mentioned as a therapeutic option.
- Norrbrink (2009) assessed the short-term effects of HF and low-frequency (LF) TENS for neuropathic pain following spinal cord injury (SCI). A total of 24 patients participated in the study. According to the protocol, 50 % of the patients were assigned to HF (80 Hz) and 50 % to LF (burst of 2 Hz) TENS. Patients were instructed to treat themselves 3 times daily for 2 weeks. After a 2-week wash-out period, patients switched stimulation frequencies and repeated the procedure. Results were calculated on an intent-to-treat basis. No differences between the 2 modes of stimulation were found. On a group level, no effects on pain intensity ratings or ratings of mood, coping with pain, life satisfaction, sleep quality, or psychosocial consequences of pain were seen. However, 29 % of the patients reported a favorable effect from HF and 38 % from LF stimulation on a 5-point global pain-relief scale.
- Six of the patients (25 %) were, at their request, prescribed TENS stimulators for further treatment at the end of the study. The authors concluded that TENS merits consideration as a complementary treatment in patients with SCI and neuropathic pain. The mild benefits observed - 29 % of subjects in the HF group and 38 % of subjects in the LF group could be a placebo effect.
- Moharic and Burger (2010) examined if TENS improves small fiber function diminished because of painful diabetic neuropathy. A total of 46 patients with painful diabetic neuropathy were treated with TENS 3 consecutive hours a day for 3 weeks. Treatment effect was evaluated with cold, warm, cold pain and heat pain thresholds, vibration perception thresholds and touch perception thresholds. In all patients, thermal-specific and thermal pain sensitivity determination showed quantitative and qualitative abnormalities in all the measured spots. After the TENS therapy, no statistically significant changes in cold, warm, cold pain, heat pain, vibratory perception and touch perception thresholds were observed in the stimulated area. TENS did not alter C, A α nor A β fiber-mediated perception thresholds. The authors noted that the observed changes at the thenar were probably because of central mechanisms. In general, analgesic mechanisms of TENS are likely to be complex.
- Jin et al (2010) evaluated the effectiveness of TENS on diabetic peripheral neuropathy (DPN). Randomized controlled trials (RCTs) comparing TENS with routine care, pharmacological interventions or placebo devices on patients with symptomatic DPN, were identified by electronic and manual searches. Studies were selected and available data were extracted independently by 2 investigators. Meta-analysis was performed by RevMan 4.2.8 software. A total of 3 RCTs involving 78 patients were included in this study. The reductions in mean pain score were

significantly greater in TENS group than in placebo TENS group in 4 weeks and 6 weeks follow-up [4 weeks, SMD-5.37, 95 % CI: -6.97 to -3.77; 6 weeks, SMD-1.01, 95 % CI: -2.01 to -0.01]], but not in 12 weeks follow-up [SMD-1.65, 95 % CI: -4.02 to 0.73]. TENS therapy was associated with significantly subjective improvement in overall neuropathic symptoms in 12 weeks follow-up [WMD-0.18, 95 % CI: -0.32 to -0.051].

- No TENS-related adverse events were registered in TENS group. The authors concluded that TENS therapy may be an effective and safe strategy in treatment of symptomatic DPN. They stated that due to small sample and short-term treatment duration, large multi-center RCTs are needed to further evaluate the long-term effect of TENS on DPN.
- Johnson and Bjordal (2011) stated that the management of neuropathic pain is challenging, with medication being the first-line treatment. Transcutaneous electrical nerve stimulation is a non-invasive, self-administered technique that is used as an adjunct to medication. Clinical experience suggested that TENS is beneficial providing it is administered at a sufficiently strong intensity, close to the site of pain. At present, there are too few RCTs on TENS for neuropathic pain to judge effectiveness. The findings of systematic reviews of TENS for other pain syndromes are inconclusive because trials have a low fidelity associated with inadequate TENS technique and infrequent treatments of insufficient duration. The use of electrode arrays to spatially target stimulation more precisely may improve the efficacy of TENS in the future.
- In a systematic review, Abou-Setta (2011) reviewed the benefits and harms of pharmacological and non-pharmacological interventions for managing pain after hip fracture. A total of 25 electronic databases (January 1990 to December 2010), gray literature, trial registries, and reference lists, with no language restrictions were searched. Multiple reviewers independently and in duplicate screened 9,357 citations to identify RCTs; non-RCTs; and cohort studies of pain management techniques in older adults after acute hip fracture. Independent, duplicate data extraction and quality assessment were conducted, with discrepancies resolved by consensus or a third reviewer. Data extracted included study characteristics, inclusion and exclusion criteria, participant characteristics, interventions, and outcomes.
- A total of 83 unique studies (64 RCTs, 5 non-RCTs, and 14 cohort studies) were included that addressed nerve blockade ($n = 32$), spinal anesthesia ($n = 30$), systemic analgesia ($n = 3$), traction ($n = 11$), multi-modal pain management ($n = 2$), neurostimulation ($n = 2$), rehabilitation ($n = 1$), and complementary and alternative medicine ($n = 2$). Overall, moderate evidence suggested that nerve blockades are effective for relieving acute pain and reducing delirium. Low-level evidence suggested that pre-operative traction does not reduce acute pain. Evidence was insufficient on the benefits and harms of most interventions, including spinal anesthesia, systemic analgesia, multi-modal pain management, acupuncture, relaxation therapy, TENS, and physical therapy regimens, in managing acute pain.
- The authors concluded that nerve blockade seems to be effective in reducing acute pain after hip fracture. Sparse data preclude firm conclusions about the relative benefits or harms of many other pain management interventions (including TENS) for patients with hip fracture.
- Interferential stimulation (IFS) is characterized by 2 alternating-current sine waves of differing frequencies that "work" together to produce an interferential current that is also known as a beat pulse or alternating modulation frequency. One of the 2 currents is usually 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 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.
- It has been claimed that IFS is highly effective in reducing (i) pain and use of pain medications, (ii) edema and inflammation, (iii) healing time, as well as in improving (i) range of motion, (ii) activity levels, and (iii) quality of life. However, there are very few well designed studies such as randomized, double blind, controlled clinical trials that support such claims. Low (1988) stated

that in spite of widespread agreement among physiotherapists that IFS has a marked pain relieving effect, there is a paucity of objective investigations into this analgesic effect. He claimed that both the therapeutic and physiological effects of interferential currents require further investigation. This notion is echoed by Goats (1990) who reported that evidence supporting the use of IFS in the control of edema appears mainly anecdotal. Reitman and Esses (1995) noted that there were no controlled studies proving the effectiveness of IFS.

- Indergand and Morgan (1995) reported that interferential current applied over the stellate ganglion did not change forearm hemodynamics in asymptomatic individuals. The authors stated that these findings challenged the concept that IFS can block sympathetic vasoconstrictor impulses in peripheral nerves.
- In a randomized placebo controlled study, Van Der Heijden et al (1999) evaluated the effectiveness of bipolar interferential electrotherapy (ET) and pulsed ultrasound (US) as adjuvants to exercise therapy for soft tissue shoulder disorders (n = 180). Patients with shoulder pain and/or restricted shoulder mobility, because of soft tissue impairment without underlying specific or generalized condition, were randomised to receive (i) active ET plus active US; (ii) active ET plus dummy US; (iii) dummy ET plus active US; (iv) dummy ET plus dummy US; or (v) no adjuvants. Additionally, they received a maximum of 12 sessions of exercise therapy in 6 weeks. Measurements at baseline, 6 weeks and 3, 6, 9, and 12 months later were blinded for treatment. Outcome measures: recovery, functional status, chief complaint, pain, clinical status, and range of motion.
- At the 6th-week, 7 patients (20 %) without adjuvants reported very large improvement (including complete recovery), 17 (23 %) and 16 (22 %) with active and dummy ET, and 19 (26 %) and 14 (19 %) with active and dummy US. These proportions increased to about 40 % at the 3rd-months, but remained virtually stable thereafter. The authors concluded that neither ET nor US proved to be effective as adjuvants to exercise therapy for soft tissue shoulder disorders.
- Jarit et al (2003) concluded that home IFS may help reduce pain, pain medication taken, and swelling while increasing range of motion in patients undergoing knee surgery. This could result in quicker return to activities of daily living and athletic activities. Drawbacks of this study were as follows: (i) while placebo subjects did consume more medications at all time points, the difference was only at some points, and (ii) a functional assessment scale was not used. The findings of this study need to be validated by further investigation. Furthermore, a technology assessment by the California Technology Assessment Forum (CTAF, 2005) concluded that interferential stimulation does not meet CTAF's assessment criteria.
- A review on non-pharmacological therapies (including IFS) for acute and chronic LBP by the American Pain Society and the American College of Physicians (Chou et al, 2007) concluded that therapies with good evidence of moderate efficacy for chronic or sub-acute LBP are cognitive-behavioral therapy, exercise, spinal manipulation, and inter-disciplinary rehabilitation. For acute LBP, the only therapy with good evidence of efficacy is superficial heat.
- Guidelines on treatment of LBP from the National Collaborating Centre for Primary Care (Savigny et al, 2009) found insufficient evidence for the use of interferential stimulation in LBP and recommended against its use for that indication.
- In a systematic review and meta-analysis, Fuentes et al (2010) analyzed the available information regarding the efficacy of IFS in the management of musculoskeletal pain. Randomized controlled trials were obtained through a computerized search of bibliographic databases (i.e., CINAHL, Cochrane Library, EMBASE, MEDLINE, PEDro, Scopus, and Web of Science) from 1950 to February 8, 2010. Two independent reviewers screened the abstracts found in the databases. Methodological quality was assessed using a compilation of items included in different scales related to rehabilitation research. The mean difference, with 95 % confidence interval (CI), was used to quantify the pooled effect. A chi-square test for heterogeneity was performed. A total of 2,235 articles were found.
- A total of 20 studies fulfilled the inclusion criteria; 7 articles assessed the use of IFS on joint pain; 9 articles evaluated the use of IFS on muscle pain; 3 articles evaluated its use on soft tissue shoulder pain; and 1 article examined its use on post-operative pain. Three of the 20 studies were

considered to be of high methodological quality, 14 studies were considered to be of moderate methodological quality, and 3 studies were considered to be of poor methodological quality. Fourteen studies were included in the meta-analysis. The authors concluded that IFS as a supplement to another intervention seems to be more effective for reducing pain than a control treatment at discharge and more effective than a placebo treatment at the 3-month follow-up.

- However, it is unknown whether the analgesic effect of IFS is superior to that of the concomitant interventions. Interferential current alone was not significantly better than placebo or other therapy at discharge or follow-up. Results must be considered with caution due to the low number of studies that used IFS alone. In addition, the heterogeneity across studies and methodological limitations prevent conclusive statements regarding analgesic efficacy.
- Percutaneous electrical nerve stimulation (also known as percutaneous neuromodulation) uses acupuncture-like needles as electrodes. These needles are placed in the soft tissues or muscles at dermatomal levels corresponding to local pathology (needles are usually inserted above and below and into the central area of pain). A 5-Hz frequency with a pulse width of 0.5 mS is usually used. If relief is not attained within 15 minutes, the frequency may be lowered to 1 Hz. According to PENS proponents, the main advantage of PENS over TENS is that it bypasses the local skin resistance and delivers electrical stimuli at the precisely desired level in close proximity to the nerve endings located in soft tissue, muscle, or periosteum of the involved dermatomes.
- Percutaneous electrical nerve stimulation has also been used in the treatment of neck pain; however, there is insufficient evidence to support its effectiveness for this indication. Harris and Susman (2002) stated that the Philadelphia Panel recently formulated evidence-based guidelines for selected rehabilitation interventions in the management of low back, knee, neck, and shoulder pain. The guidelines were developed with the use of a 5-step process: (i) define the intervention, (ii) collect evidence, (iii) synthesize results, (iv) make recommendations based on the research, and (v) grade the strength of the recommendations. Outpatient adults with low back, knee, neck, or shoulder pain without vertebral disk involvement, scoliosis, cancer, or pulmonary, neurological, cardiac, dermatological, or psychiatric conditions were included in the review. To prepare the data, systematic reviews were performed for low back, knee, neck, and shoulder pain.
- Therapeutic exercise, massage, transcutaneous electrical nerve stimulation, thermotherapy, ultrasound, electrical stimulation, and combinations of these therapies were included in the literature search. Studies were identified and analyzed based on study type, clinical significance, and statistical significance. The authors concluded that the Philadelphia Panel guidelines recommend continued normal activity for acute, uncomplicated LBP and therapeutic exercise for chronic, subacute, and post-surgical LBP; TENS and exercise for knee osteoarthritis; proprioceptive and therapeutic exercise for chronic neck pain; and the use of therapeutic ultrasound in the treatment of calcific tendonitis of the shoulder.
- Weiner and Ernst (2004) reviewed common complementary and alternative treatment modalities for the treatment of persistent musculoskeletal pain in older adults. A critical review of the literature on acupuncture and related modalities, herbal therapies, homeopathy, and spinal manipulation was carried out. Review included 678 cases within 21 randomized trials and 2 systematic reviews of herbal therapies; 798 cases within 2 systematic reviews of homeopathy; 1,059 cases within 1 systematic review of spinal manipulation for LBP, and 419 cases within 4 randomized controlled trials for neck pain. The review of acupuncture and related modalities was based upon a paucity of well-controlled studies combined with the authors' clinical experience. Insufficient experimental evidence exists to recommend the use of traditional Chinese acupuncture over other modalities for older adults with persistent musculoskeletal pain.
- Promising preliminary evidence exists to support the use of percutaneous electrical nerve stimulation for persistent LBP. The authors noted that while the use of complementary and alternative modalities for the treatment of persistent musculoskeletal pain continues to increase, rigorous clinical trials examining their effectiveness are needed before definitive recommendations regarding the application of these modalities can be made.
- According to the Washington State Department of Labor and Industries (2004), percutaneous neuromodulation therapy, also known as PENS, is a procedure intended to relieve and manage

chronic or intractable LBP; chronic neck pain was not mentioned as an indication. Furthermore, a Cochrane review on electrotherapy for mechanical neck disorders (Kroeling et al, 2005) evaluated if electrotherapy relieves pain or improves function/disability in adults with mechanical neck disorders (MND). For the pain outcome, there was limited evidence of benefit, i.e., pulsed electromagnetic field (PEMF) therapy resulted in only immediate post-treatment pain relief for chronic MND and acute whiplash (WAD).

- Other findings included unclear or conflicting evidence (galvanic current for acute or chronic occipital headache; iontophoresis for acute, subacute WAD; TENS for acute WAD, chronic MND; PEMF for medium- or long-term effects in acute WAD, chronic MND); and limited evidence of no benefit (diadynamic current for reduction of trigger point tenderness in chronic MND, cervicogenic headache; permanent magnets for chronic MND; electrical muscle stimulation (EMS) for chronic MND). The authors concluded that in pain as well as other outcomes, the evidence for treatment of acute or chronic MND by different forms of electrotherapy is either lacking, limited, or conflicting.
- The National Institute for Health and Clinical Excellence's assessment on "Percutaneous electrical nerve stimulation for refractory neuropathic pain" (NICE, 2013) stated that "Current evidence on the safety of percutaneous electrical nerve stimulation (PENS) for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term. Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit".
- Peripherally implanted nerve stimulation entails the placement of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit that is inserted subcutaneously at a depth not greater than half an inch. Stimulation is elicited by a generator that is connected to an antenna that is attached to the skin surface over the receiver unit. Sciatic and ulnar nerves are often the sites of such an implantation.
- H-wave stimulation delivers electrical stimulation in the form of milliamperage. H-wave stimulation is intended to emulate the H wave found in nerve signals (Hoffman Reflex) and therefore enables greater and deeper penetration of a low frequency current, while using significantly less power than other machines. This allegedly makes H-Wave stimulation much safer, less painful and more effective than other forms of electrotherapy to date. The H-wave signal is a bipolar, exponential decaying waveform that supposedly overcomes the disadvantages of other electrotherapy machines. It allows the therapist to apply 2 treatments at the same time: (i) low-frequency muscle stimulation and (ii) high-frequency deep analgesic pain control (a "TENS" effect). Note: H-wave stimulation must be distinguished from the H-waves that are a component of electromyography.
- The H-wave stimulator (Electronic Waveform Lab, Inc., Huntington Beach, CA) is an electrostimulation device that has been used to reduce pain and swelling associated with a variety of diseases and conditions. In a single-blinded clinical study, Kumar and Marshall (1997) evaluated the effectiveness of H-wave stimulation for the treatment of chronic (greater than 2 months) pain associated with diabetic (type 2) peripheral neuropathy (n = 31). Patients were randomly assigned to (i) H-wave stimulation, or (ii) sham treatment. The authors reported that H-wave treated patients exhibited greater symptomatic relief than their sham-treated counterparts. Moreover, it has also been shown that H-wave stimulation may be a useful adjunctive modality when combined with pharmacotherapy (e.g., amitriptyline) to augment symptomatic relief in patients with diabetic peripheral neuropathy (Julka et al, 1998; McDowell et al, 1999).
- On the other hand, H-wave stimulators have not been shown to be effective in reducing pain from causes other than chronic diabetic peripheral neuropathy, or in reducing edema or swelling. In particular, H-wave stimulation has not been demonstrated to be effective in treating chronic pain due to ischemia. In the study by Kumar and Marshall (1997), patients with significant peripheral vascular disease were excluded from the trial. Furthermore, in a randomized controlled study (n = 112), McDowell et al (1995) reported that H-wave stimulation was not effective in reducing experimental ischemic pain.

- A systematic evidence review concluded that H-wave stimulation had a moderate to strong effects in relieving pain, reducing pain medication use and increasing functionality in patients with chronic soft tissue inflammation or neuropathic pain (Blum et al, 2008). A critique of this systematic evidence review by the Centre for Reviews and Dissemination (CRD, 2009) concluded that "it is not possible to determine whether the results of this review are reliable" given its significant methodologic limitations. In particular, very limited details of the included studies were given in the review; in particular it was unclear which studies were randomized, no control interventions were detailed, and there were insufficient details on the outcome measures used. Although a validity assessment was performed, the results were not presented. "Given these omissions, it is difficult to assess either the internal or external validity of the results."
- The CRD noted that the authors of the systematic evidence review used meta-analysis to combine the results, but different measures of effect appeared to be combined in a single effect size. Insufficient details on the outcome measures used in the included studies meant that it was not possible to determine if this was appropriate or not. The CRD critique noted that, in addition to four authors of the systematic evidence review being independent consultants for Electronic Waveform Lab (the makers of the H-Wave device), 2 authors were members of the research groups responsible for conducting the primary studies.
- Intramuscular stimulation can be considered as a variation of acupuncture. It has been claimed to promote long-term relief in chronic neuropathic pain. Intramuscular stimulation utilizes the same sized needles as in acupuncture; they are inserted into the part of a shortened muscle where a nerve may be entrapped. This most often causes some local pain as the needle is re-inserted several times to release the nerve and lengthen the muscle. In general, treatments are administered once or twice weekly for 3 to 6 weeks. However, the clinical value of this invasive procedure has not been validated by randomized controlled studies.
- Many chronic pain syndromes/conditions (e.g., peripheral neuropathies and reflex sympathetic dystrophy) are "sympathetically biased" and have no identifiable underlying cause(s).
- Sympathetic Therapy is a non-invasive treatment protocol advocated for the symptomatic relief of patients with chronic pain. It is a patented method of delivering electrostimulation via peripheral nerves to create a "special" form of stimulation of the sympathetic nervous system. It incorporates dual interfering waveforms with specific electrode placement on the upper and lower extremities (8 electrodes/treatment). Electrodes are placed bilaterally over dermatomes, thus accessing the autonomic nervous system via the peripheral nervous system.
- The treatment plan for Sympathetic Therapy includes clinical treatments followed by home therapy. Electrostimulation is administered by means of the Dynatron STS (a clinical unit) or the Dynatron STS Rx (a home unit). A software program is included with the clinical Dynatron unit to help doctors with electrode placement and to record patient progress. According to the manufacturer, electrostimulation delivered by the Dynatron is different from that provided by TENS. The key difference is in its application -- Dynatron applied within the Sympathetic Therapy protocol supposedly treats systemically while TENS treats transcutaneously at or near the primary pain location. Daily therapy sessions are needed to establish effectiveness of the treatment and to ascertain the most effective protocol for individual patients (20 or more sessions may be needed to complete this process). Each treatment session lasts about 60 mins.
- If the patient responds to treatment and the optimal protocol has been established, a home Dynatron unit may be prescribed to facilitate treatments over an extended period of time and, in most cases, indefinitely. If necessary, the patient may return to the clinic periodically for a follow-up visit to adjust the protocol or receive additional guidance in administering home therapy.
- Guido (2002) reported on the effects of Sympathetic Therapy on 20 patients with chronic pain and peripheral neuropathies. Subjects were treated daily with the Dynatron STS for 28 days. At the beginning of the study, 11 of 15 patients reported being in moderate to severe pain, whereas by the end of treatment, 5 of 15 patients defined their pain as being moderate to severe. For these 15 patients, mean cumulative VAS for multiple locations of pain decreased significantly, from 107.8 to 45.3. (The authors stated, without further explanation, that self-reports of pain severity were unavailable for 5 of the 20 patients.) However, because the study did not include a

randomized masked control group, placebo effects and other biases could affect results. In addition, the lack of data on pain severity in a quarter of the patients included in this study may have significantly biased the results.

- There are no published randomized controlled clinical trials of the effectiveness of Sympathetic Therapy in the management of patients with chronic intractable pain. Randomized controlled trials are needed to ascertain the clinical benefits of this treatment protocol in these patients.
- An assessment (2003) conducted by the Washington State Department of Labor and Industries concluded that insufficient evidence exists to determine Dynatron STS' effectiveness in the treatment of chronic pain.
- Guidelines on management of chronic pain from the Work Loss Data Institute (2008) considered, but did not recommend, sympathetic therapy for chronic pain.
- Electroceutical medicine entails the use of various electrical modalities. While certain "low-strength" electrical treatments such as transcutaneous electrical nerve stimulation (TENS) units may be safely used at home, electroceutical treatments use much higher electrical frequencies than TENS units (ranging from 1 to 20,000 Hz compared to 0.5 to 100 Hz used in TENS) and may only be prescribed and administered under the supervision of a healthcare provider experienced in this method of treatment.
- Electroceutical therapy, also known as bioelectric nerve block, involves blockade of axonal transmissions. Electroceutical therapy has been used in the management of neuropathic pain (non-malignant pain) as well as pain associated with cancer (malignant pain). According to a manufacturer of an electroceutical nerve block device, the electroceutical treatment approach is based on the non-invasive application of controlled, specific parameter bioelectric impulses. Electrical current is altered via special step-down transformers into bioelectric impulses, which are designed to mimic the human bioelectric system. Currently, there are 2 distinctive electroceutical classifications: (i) stimulatory class in which repetitive action potentials are induced in excitable cells (depolarization and repolarization activity), and (ii) multi-facilitory class that produces biophysical effects without repetitive action potential propagation.
- The proper electroceutical class, dosage, regimen duration and anatomical placement of electrodes are determined by the individual patient's diagnosis.
- Proponents of electroceutical therapy claim that its use has resulted in significant relief of pain and elimination or drastic reductions in patients' pain medication requirements, such that patients are able to resume their daily activities. However, there is a lack of scientific evidence to substantiate these claims. Guidelines from the Work Loss Data Institute (2008) considered, but did not recommend, electroceutical therapy for chronic pain.
- Well-designed, randomized controlled clinical studies are needed to determine the usefulness of electroceutical therapy in the treatment of patients with acute or chronic pain.
- Transcutaneous electrical joint stimulation is also known as pulsed electrical stimulation; and the Bionicare device uses this type of electrical stimulation. Zizic et al (1995) evaluated the safety and effectiveness of pulsed electrical stimulation for the treatment of osteoarthritis (OA) of the knee ($n = 78$). Patients were treated 6 hours/day for 4 weeks. The investigators reported that patients treated with the active devices showed significantly greater improvement than the placebo group for all primary efficacy variables in comparisons of mean change from baseline to the end of treatment. Improvement of greater or equal to 50 % from baseline was shown in at least 1 primary efficacy variable in 50 % of the active device group, in 2 variables in 32 %, and in all 3 variables in 24 %. In the placebo group improvement of greater or equal to 50 % occurred in 36 % for one, 6 % for 2, and 6 % for 3 variables.
- Mean morning stiffness decreased 20 mins in the active device group and increased 2 mins in the placebo group ($p < 0.05$). No statistically significant differences were observed for tenderness, swelling, or walking time. The authors concluded that improvements in clinical measures for pain and function found in this study suggest that pulsed electrical stimulation is effective for treating OA of the knee. The investigators noted, however, that studies of the durability of results are warranted.

- In a Cochrane review on pulsed electric stimulation for the treatment of OA (Hulme et al, 2002), the authors stated that current evidence suggests that electrical stimulation therapy may provide significant improvements for knee OA, but further studies are required to confirm whether the statistically significant results shown in these trials confer clinically significant and durable benefits.
- A systematic evidence review by McCarthy et al (2006) concluded that pulsed electromagnetic field therapy is unlikely to benefit patients with knee osteoarthritis. The systematic evidence review identified 5 RCTs of pulsed electromagnetic field therapy for knee osteoarthritis: 2 RCTs scored 5 points for validity, 1 scored 4 and 2 scored 3. The investigators found that none of the individual studies reported a statistically significant difference between treatments for pain. Only 1 study (n = 83) with a low quality score of 3 reported a statistically significant difference between treatments in function (standardized mean difference -0.58, 95 % CI: -1.02 to -0.14). For all studies combined, there was no significant difference between interventions in pain (weighted mean difference -0.66, 95 % CI: -1.67 to 0.35) or function (weighted mean difference -0.70, 95 % CI: -1.92 to 0.52).
- Fary and colleagues (2008) stated that OA of the knee is one of the main causes of musculoskeletal disability in the western world. Current available management options provide symptomatic relief (exercise and self-management, medication and surgery) but do not, in general, address the disease process itself. Moreover, adverse effects and complications with some of these interventions (medication and surgery) and the presence of co-morbidities commonly restrict their use. There is clearly a need to investigate treatments that are more widely applicable for symptom management and which may also directly address the disease process itself. The authors described the protocol of a double-blind, randomized, placebo-controlled, repeated measures trial to examine the effectiveness of pulsed electrical stimulation in providing symptomatic relief for people with OA of the knee over 26 weeks.
- A total of 70 subjects will be recruited and information regarding age, gender, body mass index and medication use will be recorded. The population will be stratified for age, gender and baseline pain levels. Outcome measures will include pain (100 mm VAS and WOMAC 3.1), function(WOMAC 3.1), stiffness (WOMAC 3.1), patient global assessment (100 mm VAS) and quality of life (SF-36). These outcomes will be measured at baseline, 4, 16 and 26 weeks. Activity levels will be measured at baseline and 16 weeks using accelerometers and the Human Activity Profile questionnaire. A patient global perceived effect scale (11-point Likert) will be completed at 16 and 26 weeks.
- The Electro-Acuscope Myopulse Therapy System is an electronic device that has been used for a wide range of neuromuscular conditions. The Acuscope uses electricity to treat pain by stimulating the nervous system without puncturing the skin. The Myopulse, a companion instrument to the Acuscope, stimulates muscles, tendons and ligaments, reducing spasm, inflammation and strengthening tissue damaged by traumatic injury. This form of therapy purportedly helps the body heal itself by stimulating the supply of blood and oxygen to the involved area. The Electro-Acuscope Myopulse Therapy System has been used in the treatment of pain and many types of tissue damage including swelling, inflammation, and soreness. However there is insufficient scientific evidence to support its effectiveness.
- Electrical stimulation of the sacral nerves (sacral neuromodulation) or lumbosacral plexus has been used for painful conditions resulting from chronic abdominal, pelvic, genital, and anal pain syndromes (Kim, 2004). Specific conditions that have been treated include pain from interstitial cystitis, coccydynia, pyelonephritis, pancreatitis, rectal fugax, and vulvodynia.
- Procedures allowing access to sacral and lumbosacral nerves include a retrograde (cephalocaudal) epidural approach and a sacral transforaminal approach. The transforaminal approach is mainly used for the treatment of urge urinary incontinence and urinary retention, while the retrograde approach has been used primarily for the treatment of pelvic pain.
- Evidence for sacral nerve root and lumbosacral plexus stimulation is limited to case reports and small case series. Alo and colleagues (1999) reported that lumbar and sacral nerve root stimulation through the retrograde approach resulted in adequate paresthesia and effective pain

relief as reflected by VAS scores in 5 patients with chronic pain (e.g., ilioinguinal neuralgia, discogenic LBP, failed back syndrome, and vulvodynia). These investigators concluded that further clinical trials are needed to assess the safety and long-term success rates of lumbar/sacral nerve root stimulation in the management of patients with chronic pain.

- Anterograde sacral nerve root stimulation (SNRS) through the sacral hiatus is another method that has been tried for the treatment of pelvic pain. In a case report study, Falco et al (2003) found that anterograde SNRS provided good pain relief (as indexed by VAS scores) in a patient with chronic pelvic (rectal, coccygeal, and perineal) pain. The authors concluded that further investigation is needed before any conclusions can be rendered regarding the reliability of SNRS in the treatment of these disorders.
- Siegel and colleagues (2001) examined the effectiveness of transforaminal sacral nerve stimulation in patients with chronic intractable pelvic pain. After successful percutaneous trial stimulation, a neuroprosthetic sacral nerve stimulation device was surgically implanted in 10 patients with chronic intractable pelvic pain. Leads were placed in the S3 and S4 foramen in 8 and 2 cases, respectively. Patients were evaluated throughout the study using a patient pain assessment questionnaire on a scale of 0 (absence of pain) to 5 (excruciating pain). Pain was assessed at baseline, during test stimulation, and 1, 3 and 6 months after implantation of surgical lead. An additional long-term assessment was done at a median follow-up of 19 months. Of the 10 patients with the implant, 9 had a decrease in the severity of the worst pain compared to baseline at a median follow-up of 19 months. The number of hours of pain decreased from 13.1 to 6.9 at the same follow-up interval.
- There was also an average decrease in the rate of pain from 9.7 at baseline to 4.4 on a scale of 10 (always having pain) to 0 (never having pain). At a median of 19 months, 6 of 10 patients reported significant improvement in pelvic pain symptomatology. The authors concluded that these data imply that transforaminal sacral nerve stimulation can have beneficial effects on the severity and frequency of chronic intractable pelvic pain. They further stated that future clinical studies are necessary to determine the long-term effectiveness of this therapy.
- The available evidence on sacral nerve root and lumbosacral plexus stimulation is insufficient to draw reliable conclusions about the effect of these interventions on chronic pelvic and abdominal pain.
- Microcurrent therapy (MCT), also known as low-voltage microampere stimulation, is characterized by sub-sensory current that acts on the body's naturally occurring electrical impulses to decrease pain and facilitate the healing process. It uses microamperage instead of milliamperage to drive its current into the injured site. Microcurrent therapy uses current between 1 and 1,000 microA at a voltage of 10 to 60 V, and a frequency of 0.5 to 100 Hz. It differs from TENS in that it uses a significantly reduced electrical stimulation. While TENS blocks pain, MCT acts on the naturally occurring electrical impulses to decrease pain by stimulating the healing process.
- Koopman et al (2009) stated that MCT is a novel treatment for pain syndromes. The MCT patch is hypothesized to produce stimuli that promote tissue healing by facilitating physiologic currents. Solid evidence from randomized clinical trials is lacking. To assess the effectiveness of MCT in treating non-specific, chronic LBP, these researchers conducted a double-blind, randomized, cross-over, pilot trial. A total of 10 succeeding patients presenting with non-specific, chronic LBP were included. Patients started with 2, 9-day baseline period followed by a 5-day treatment periods. During the treatment periods, either a placebo or MCT (verum) patch was randomly assigned. Mean and worst pain scores were evaluated daily by a VAS. Furthermore, analgesic use, side effects, and quality of life were assessed after each period. Differences between the last 4 days of a treatment period and the baseline period were calculated.
- Differences between verum and placebo periods per patient were compared using paired-t tests. A 20-mm VAS score reduction was considered clinically relevant. The VAS score was lower during verum treatment, with a reduction (95 % CI) of -0.43 (-1.74; 0.89) in mean and -1.07 (-2.85; 0.71) in worst pain. Analgesic use decreased during verum treatment, except for non-steroid anti-inflammatory drug use, which increased. Quality of life improved during verum

treatment. However, none of the findings was statistically significant. A positive trend in MCT use for aspecific, chronic LBP was reported. The authors stated that further investigations are needed to evaluate the significance and relevance of these findings.

- Furthermore, the American Pain Society's clinical practice guideline on non-surgical interventional therapies for LBP (Chou et al, 2009) concluded that few non-surgical interventional therapies for LBP have been shown to be effective in randomized, placebo-controlled trials.
- Zuim et al (2006) evaluated the effect of microcurrent electrical nerve stimulation (MENS) and compared with occlusal splint therapy in temporo-mandibular disorders (TMD) patients with muscle pain. A total of 20 TMD patients were divided into 4 groups. One received occlusal splint therapy and MENS (I); other received splints and placebo MENS (II); the third, only MENS (III) and the last group, placebo MENS (IV). Sensitivity derived from muscle palpation was evaluated using a VAS. Results were submitted to analysis of variance ($p < 0.05$). There was reduction of pain level in all groups: group I (occlusal splint and MENS) had a 47.7 % reduction rate; group II (occlusal splint and placebo MENS), 66.7 %; group III (MENS), 49.7 % and group IV (placebo MENS), 16.5 %. In spite of that, there was no statistical difference (analysis of variance/ $p < 0.05$) between MENS and occlusal splint therapy regarding muscle pain reduction in TMD patients after 4 weeks.
- In a placebo-controlled, single-blinded, and randomized study, Gossrau et al (2011) evaluated the effect of micro-TENS in reducing neuropathic pain in patients with painful diabetic neuropathy (PDN). A total of 22 diabetic patients have been treated with a micro-TENS therapy and 19 patients have been treated with a placebo therapy. Treatment duration was 4 weeks with 3 therapeutic settings per week. Standardized questionnaires (Pain Disability Index [PDI], neuropathic pain score [NPS], Center for Epidemiologic Studies Depression Scale [CES-D]) were used to assess pain intensity, pain disability, as well as quality of life at baseline at the end of the treatment period and 4 weeks after treatment termination. Patients with a minimum of 30 % reduction in NPS were defined as therapy responders. After 4 weeks of treatment, 6/21 (28.6 %) patients in the verum group versus 10/19 (52.6 %) patients in the placebo group responded to therapy.
- The median PDI score after 4 weeks of treatment showed a reduction of 23 % in the verum versus 25 % in the placebo group. The differences did not reach statistical significance. The authors concluded that the pain reduction with the applied transcutaneous electrotherapy regimen is not superior to a placebo treatment.
- Scrambler therapy (also known as transcutaneous electrical modulation pain reprocessing) is an electro-cutaneous nerve stimulation device that interferes with pain signal transmission by mixing a "non-pain" information into the nerve fibers. It consists of a multi-processor apparatus capable of simulating 5 artificial neurons that send out signals identified by the central nervous system as "no pain" via the application of surface electrodes on skin in the pain areas.
- Marineo (2003) examined the effects of the Scrambler therapy in the treatment of drug-resistant oncological pain of the visceral/neuropathic type. A total of 11 terminal cancer patients (3 pancreas, 4 colon, 4 gastric) suffering from elevated drug resistant visceral pain were included in this study. The trial program was related to the first 10 treatment sessions. Subsequently, each patient continued to receive treatment until death. Pain measures were performed using the VAS before and after each treatment session and accompanied by diary recordings of the duration of analgesia in the hours following each single application. Any variation in pain-killing drug consumption was also recorded. All patients reacted positively to the treatment throughout the whole reference period. Pain intensity showed a significant decrease ($p < 0.001$), accompanied by a gradual rise both in the pain threshold and the duration of analgesia.
- Nine (81.8 %) of the patients suspended pain-killers within the first 5 applications, while the remaining 2 (18.2 %) considerably reduced the dosage taken prior to scrambler therapy. No undesirable side effects were observed. Compliance was found to be optimal. The authors concluded that these preliminary results obtained using scrambler therapy were extremely encouraging, both in terms of enhanced pain control after each treatment session and in view of the possible maintenance of effectiveness over time.

- Sabato et al (2005) assessed the effectiveness of the Scrambler therapy in the treatment of neuropathic pain. A total of 226 patients, all suffering from intense drug-resistant neuropathic pain, were recruited for this trial. Inclusion criteria included neuropathic pain, very high baseline VAS. Exclusion criteria included pacemaker users, neurolytic blocks or neurolesive pain control treatment. The treated neuropathic pain syndromes were: failed back surgery syndrome (FBSS), post-herpetic neuralgia (PHN), trigeminal neuralgia, post-surgery nerve lesion neuropathy, pudendal neuropathy, brachial plexus neuropathy, LBP, and others. The trial program entailed 1 to 6 therapy sessions of 5 treatments, each one lasting 30 mins. Pain intensity was evaluated using VAS before and after each treatment. The statistical significance of VAS was measured using the paired t-test.
- The total results showed 80.09 % of responders (pain relief greater than 50 %), 10.18 % of partially responders (pain relief from 25 % to 49 %) and 9.73 % of no responders (patients with pain relief less than 24 % or VAS greater than 3). The authors concluded that the Scrambler therapy produced a statistically significant ($p < 0.0001$) pain relief in all treated neuropathies.
- In a pilot study, Marineo et al (2012) compared guideline-based drug management with Scrambler therapy. A clinical trial with patients randomized to either guideline-based pharmacological treatment or Scrambler therapy for a cycle of 10 daily sessions was performed. Patients were matched by type of pain including post-surgical neuropathic pain, PHN, or spinal canal stenosis. Primary outcome was change in VAS pain scores at 1 month; secondary outcomes included VAS pain scores at 2 and 3 months, pain medication use, and allodynia. A total of 52 patients were randomized. The mean VAS pain score before treatment was 8.1 points (control) and 8.0 points (Scrambler). At 1 month, the mean VAS score was reduced from 8.1 to 5.8 (-28 %) in the control group, and from 8 to 0.7 points (-91 %) in the Scrambler group ($p < 0.0001$). At 2 and 3 months, the mean pain scores in the control group were 5.7 and 5.9 points, respectively, and 1.4 and 2 points in the Scrambler group, respectively ($p < 0.0001$).
- More relapses were seen in polyradicular pain than monoradicular pain, but re-treatment and maintenance therapy gave relief. No adverse effects were observed. The authors concluded that in this pilot randomized trial, Scrambler therapy appeared to relieve chronic neuropathic pain better than guideline-based drug management.
- In a pilot study, Smith et al (2010) evaluated the impact on chemotherapy-induced peripheral neuropathy (CIPN) associated with the MC5-A Calmare therapy device. A total of 18 patients from 1 center received 1-hour interventions daily over 10 working days. Of 18 patients, 16 were evaluable. The mean age of the patients (4 men and 14 women) was 58.6 years and the duration of CIPN was 3 months to 8 years. The most common drugs used by these subjects were taxanes, platinum, and bortezomib. At the end of the study (day 10), a 20 % reduction in numeric pain scores was achieved in 15 of 16 patients. The pain score fell 59 % from 5.81 \pm 1.11 before treatment to 2.38 \pm 1.82 at the end of 10 days ($p < 0.0001$ by paired t-test). A daily treatment benefit was seen with a strong statistically significant difference between the pre- and post-daily pain scores ($p < 0.001$). Four patients had their CIPN reduced to zero.
- A repeated-measures analysis using the scores from all 10 days confirmed these results. No toxicity was seen. Some responses have been durable without maintenance. The authors concluded that patient-specific cutaneous electro-stimulation with the MC5-A Calmare device appears to dramatically reduce pain in refractory CIPN patients with no toxicity. They stated that further studies (determining effectiveness compared with sham or placebo treatment, and the need for maintenance therapy) are underway to define the benefit, mechanisms of action, and optimal schedule. The preliminary findings of this pilot study need to be validated by well-designed studies. There is a phase II clinical trial that examines the effectiveness of the MC5-A Scrambler therapy in reducing peripheral neuropathy caused by chemotherapy.
<http://clinicaltrials.gov/ct2/show/NCT00952848>.
- Ricci et al (2012) evaluated the effectiveness of an innovative neuromodulative approach to the treatment of chronic pain using electrical stimulus integrated with pharmacological support. The MC5-A Calmare is a new device for patient-specific cutaneous electro-stimulation which, by "scrambling" pain information with "no pain" information, aims to reduce the perception of pain

intensity. These researchers prospectively treated 73 patients with cancer-related ($n = 40$) and non-cancer-related ($n = 33$) pain whose pain management was unsatisfactory. The primary objective of the study was to assess efficacy and tolerability of the device. Pain intensity was assessed daily with a Numerical Rating Scale (NRS) for the duration of treatment (2 weeks) and then on a weekly basis for the 2 weeks of follow-up.

- Mean pain value at T0 (pre-treatment value) was 6.2 [\pm 2.5 SD], 1.6 (\pm 2.0) ($p < 0.0001$) at T2 (after the 10th day of treatment), and 2.9 (\pm 2.6) ($p < 0.0001$) at T4 (after the second week of follow-up, i.e., 1 month after the beginning of treatment). Response after the second week of treatment showed a clear reduction in pain for both cancer (mean absolute delta of the reduction in NRS value = 4.0) and non-cancer (mean delta = 5.2) patients. The pain score had decreased by 74 % at T2. On the basis of pre-established response criteria, there were 78 % of responders at T2 and 81 % at T4. No side effects were reported. The authors concluded that these preliminary results suggested that cutaneous electro-stimulation with the MC5-A Calmare can be hypothesized as part of a multi-modality approach to the treatment of chronic pain.
- They stated that further studies on larger numbers of patients are needed to assess its efficacy, to quantify the effects of inter-operator variability, and to compare results obtained from the active device versus those from a sham machine.
- The InterX 1000 neurostimulator appears to be a hand-held, personal device for home use. It delivers interactive, high amplitude, high density stimulation to the cutaneous nerves, activating the body's natural pain relieving mechanisms (segmental and descending inhibition). However, there is insufficient evidence regarding its effectiveness for the treatment of chronic pain.
- Subcutaneous stimulation (peripheral nerve field stimulation/PNFS) is a novel neuromodulation modality that has increased in its utilization during the past decade. It consists of introducing a lead in the subdermal level to stimulate the small nerve fibers in that layer. Unlike other neuromodulation techniques including direct peripheral nerve stimulation, spinal cord stimulation (SCS), or deep brain stimulation, the precise target is not identified. Falco et al (2009) stated that relief of regional, non-appendicular pain, particularly LBP, through SCS has proven challenging. Recently, peripheral nerve stimulation (PNS), also known as PNFS depending on the stimulation area, has demonstrated efficacy for the treatment of well-localized, small areas of pain involving the abdomen, inguinal region, pelvis, face, occipital area, and low back.
- More widespread application of PNFS has been limited by its narrow field of coverage in a larger group of patients with diffuse or poorly localized pain.
- McRoberts and Roche (2010) described a novel approach for the treatment of severe, chronic knee joint pain following total knee arthroplasty utilizing peripheral subcutaneous field stimulation (PSFS) and discussed the role of this treatment modality in patients with symptoms that are refractory to conventional pharmacologic, surgical, and physical therapies. These researchers presented 2 case reports of patients with chronic intractable knee pain where PNS via a permanent neurostimulating implant was introduced successfully. Both patients presented with persistent knee pain, for greater than 1 year, after having had total knee arthroplasty. Their symptoms failed to be alleviated by a variety of interventions including NSAIDs, oral anti-depressants, membrane stabilizers, opioids, physical therapy, surgical revisions, manipulation under anesthesia, local anesthetic patches, and TENS.
- In each case, direct stimulation of the knee was achieved utilizing a peripheral nerve stimulator via a peri-articular approach. Neuromodulation daily has produced both significant pain relief and functional improvement. Significant decreases in VAS pain scores and improvement in functional capacity were observed during the stimulation trial and during the follow-up after permanent implantation. The mean VAS score changed dramatically. The authors concluded that introduction of PSFS directly to the painful knee area is a novel and simple procedure that was extremely effective for the relief of pain and may provide a breakthrough in the treatment of chronic intractable knee pain following total knee arthroplasty. The peri-articular approach has several advantages, including only small incisions over the lateral and medial knee, proximal thigh and abdomen resulting in minimal strain on the lead array with flexion and extension contributing to overall stability of this system.

- Yakovlev and Resch (2010) presented a case report describing application of PSFS to a patient with chronic intractable atypical facial pain (ATFP) that conventional treatment failed to ameliorate. The patient underwent an uneventful PSFS trial with percutaneous placement of 2 temporary 8-electrode leads (Medtronic Inc, Minneapolis, MN) placed subdermally over the left mandible. After experiencing excellent pain relief over the next 2 days, the patient was implanted with permanent leads and rechargeable generator 2 and a half weeks later and reported sustained pain relief at 12-month follow-up visit. Peripheral subcutaneous field stimulation provides an effective treatment option for patients suffering from chronic ATFP who have failed conservative treatment. The authors concluded that PSFS offers an alternative treatment option to select patients with intractable ATFP.
- In a retrospective study, Yakovlev et al (2010) evaluated the effectiveness of PSFS for the treatment of chronic hip pain after total hip arthroplasty (THA) and greater trochanteric bursectomy (GTB). A total of 12 patients with chronic post-operative pain after THA and GTB underwent an uneventful PSFS trial with percutaneous placement of 2 temporary 8-electrode leads positioned in the subcutaneous tissue in the area of greatest pain, parallel to post-operative scar over the affected upper lateral thigh. After experiencing excellent pain relief over the next 2 days, the patients were implanted with permanent leads and rechargeable or non-rechargeable generator 2 to 4 weeks later. They reported sustained pain relief at 12-month follow-up visits. The authors concluded that PSFS provided an effective alternative treatment option for select patients with chronic post-operative pain after THA and GTB who have failed conservative treatment.
- Ricciardo et al (2010) presented a case study to exemplify the application of PSFS in the treatment of recalcitrant notalgia paraesthetica. The patient was a 60-year old woman with severe and disabling notalgia paraesthetica. The itch persisted despite the use of several medications -- topical and oral. Following a successful trial of PSFS with a temporary electrode, 2 subcutaneous electrodes were inserted into the affected area with a battery implanted subcutaneously in her right buttock. The patient was reviewed at 5 months post-implantation. She reported a greater than 85 % improvement in her itch. She also reported a major improvement in her quality of life, with particular improvement in her ability to sleep through the night. This case illustrated the possible utilization of PSFS in the treatment of notalgia paraesthetica, which is a common yet poorly understood and treated condition.
- The authors stated that replication and controlled studies are needed to determine the general applicability of this approach.
- Goroszeniuk et al (2012) reported the use of an alternative approach to neuromodulation of anginal pain using subcutaneous leads placed at the site of pain. In this case series, 5 patients with refractory angina received successful treatment with subcutaneous target stimulation -- peripheral subcutaneous field stimulation. This technique was able to provide good analgesia in 2 patients that had had poor pain relief from existing spinal cord stimulators. All 5 patients achieved significant pain relief with a reduction in symptoms and a decrease in the use of pain medication.
- Burgher et al (2012) performed a retrospective review of consecutive patients evaluated from August 2009 to December 2010 who had undergone trial of subcutaneous (SQ) PNS with inter-lead stimulation for axial spine pain. Patients proceeding to implant were followed post-operatively with routine clinical visits and a survey form at last follow-up. Ultrasound was used intra-operatively to ensure placement of electrodes at the appropriate depth in patients with larger body mass index. Primary outcome was patient-reported pain relief at last follow-up. Literature review was conducted by searching MEDLINE (1948 to present) and through an unstructured review by the authors. A total of 10 patients underwent trial of SQ PNS and 6 proceeded to permanent implantation; 3 of the 6 (50 %) implanted patients preferred neurostimulation programming that included inter-lead stimulation ("cross-talk").
- Average duration of post-operative follow-up was 4.5 months (range of 2 to 9 months). Average patient-reported pain relief at last follow-up was 45 % (range of 20 to 80 %). One patient required re-operation for migration. Patients not proceeding to implant had paresthesia coverage but no analgesia. The authors concluded that SQ PNS is a promising therapy for axial neck and back pain based on a small cohort of patients. Ultrasound was useful to assist with electrode

placement at the most appropriate depth beneath the skin. While inter-lead stimulation has been preferred by patients in published reports, these investigators did not find it clearly influenced pain relief. The authors stated that future investigations should include a randomized, controlled study design, as well as defined implantation technique and neurostimulator programming algorithms.

- Electro-therapeutic point stimulation (ETPS), also known as microcurrent point stimulation (MPS), employs a non-invasive device to administer low-frequency direct current to acupuncture points, motor/trigger points, and contracted muscle bands. The device (known as called the ETPS 1000) has an enhanced point finder that detects treatment points on the skin and applies brief, concentrated electrical microstimulation in short bursts. This modality/approach combines the principles of acupuncture, massage, physical therapy and microcurrent stimulation. The treatment can be self-administered by the patient at home. There is insufficient peer-reviewed evidence to support the safety and effectiveness of ETPS/MPS.
- Aliyev and Geiger (2012) examined the effects of cell-stimulation therapy of lateral epicondylitis with frequency-modulated low-intensity electric current. Patients with lateral epicondylitis were subjected to a 12-week cell-stimulation therapy with low-intensity frequency-modulated electric current in addition to routine therapy. Patients in the control group received the same routine therapy and sham stimulation (the therapeutic apparatus was not energized). The effectiveness of MPS was estimated by comparing medical indices before therapy and at the end of a 12-week therapeutic course using a 10-point pain severity numeric rating scale (NRS) and Roles-Maudsley pain score.
- The study revealed high therapeutic efficiency of cell-stimulation with low-intensity electric current resulting probably from up-regulation of intracellular transmitters, interleukins, and prostaglandins playing the key role in the regulation of inflammation. The findings of this study need to be validated by well-designed studies with long-term follow-up.
- In a pilot study, Sator-Katzenschlager et al (2003) tested the hypothesis that auricular electro-acupuncture (EA) relieves pain more effectively than conventional manual auricular acupuncture. These researchers studied 21 chronic cervical pain patients without radicular symptoms with insufficient pain relief (VAS greater than 5) treated with standardized analgesic therapy. All patients received disposable acupuncture needles on the dominant side on the following acupuncture points: cervical spine, shen men, and cushion. In 10 patients, needles were continuously stimulated (2-mA constant current, 1 Hz monophasic) by using the electrical point stimulation device P-STIM. In 11 control patients, no electrical stimulation was administered. All needles were withdrawn 48 hrs after insertion. Acupuncture was performed once a week for 6 wks.
- Patients had to complete a questionnaire assessing pain intensity, psychological well-being, activity, sleep, and demand for rescue medication (lornoxepam and tramadol). The reduction in pain scores was significant in the EA group. Similarly, psychological well-being, activity, and sleep were significantly improved in patients receiving EA, and consumption of rescue medication was significantly less. These results demonstrated that continuous electrical stimulation of auricular acupuncture points by using the new point stimulation device P-STIM improves the treatment of chronic cervical pain in an outpatient population. The authors concluded that continuous electrical stimulation of auricular acupuncture points by using the new point stimulation device P-STIM significantly decreases pain intensity and significantly improves psychological well-being, activity, and sleep in chronic cervical pain patients. This was a pilot study with small number of subjects with short-term follow-up.
- In a prospective, randomized, double-blind, controlled study, Sator-Katzenschlager et al (2004) tested the hypothesis that auricular EA relieves pain more effectively than conventional manual auricular acupuncture (CO) in chronic LBP patients with insufficient pain relief (VAS greater than or equal to 5) treated with standardized analgesic therapy. Disposable acupuncture needles were inserted in the auricular acupuncture points 29, 40, and 55 of the dominant side and connected to a newly developed battery-powered miniaturized stimulator worn behind the ear. Patients were randomized into group EA (n = 31) with continuous low-frequency auricular EA (1 Hz biphasic constant current of 2 mA) and group CO (n = 30) without electrical stimulation (sham-EA).

Treatment was performed once-weekly for 6 wks, and in each group needles were withdrawn 48 hrs after insertion. During the study period and a 3-month follow-up, patients were asked to complete the McGill questionnaire.

- Psychological well-being, activity level, quality of sleep, and pain intensity were assessed by means of VAS; moreover, analgesic drug consumption was documented. Pain relief was significantly better in group EA during the study and the follow-up period as compared with group CO. Similarly, psychological well-being, activity, and sleep were significantly improved in group EA versus group CO, the consumption of analgesic rescue medication was less, and more patients returned to full-time employment. Neuropathic pain in particular improved in patients treated with EA. There were no adverse side effects. These results were the first to demonstrate that continuous EA stimulation of auricular acupuncture points improves the treatment of chronic LBP in an out-patient population.
- The authors concluded that continuous electrical stimulation of auricular acupuncture points using the new point stimulation device P-Stim significantly decreases pain intensity and improves psychological well-being, activity, and sleep in chronic LBP patients. This was a small study with a short-term follow-up.
- Sator-Katzenschlager and Michalek-Sauberer (2007) stated that acupuncture is now accepted as a complementary analgesic treatment. Auricular acupuncture is a distinct form of acupuncture. Electrical stimulation of acupoints (EA) increases the effects of acupuncture. Recently, an auricular EA device, the P-Stim, has become available. Clinical studies in outpatients have investigated the P-Stim in chronic musculo-skeletal pain and its use for minor surgery. In chronic cervical or LBP, auricular EA was more effective than conventional auricular acupuncture. The results in acute pain were controversial. Auricular EA reduced pain and remifentanyl consumption during oocyte aspiration when compared with conventional auricular acupuncture or a sham treatment.
- However, after third molar tooth extraction, auricular EA and auricular acupuncture failed to reduce either postoperative pain or analgesic consumption. The authors concluded that further large-scale studies are needed to evaluate the analgesic efficacy of auricular EA.
- Michalek-Sauberer et al (2007) examined the effects of auricular EA on pain and analgesic drug consumption in the first 48 hrs after unilateral mandibular third molar tooth extraction under local anesthesia in a prospective, randomized, double-blind, placebo-controlled study in 149 patients. Patients received either auricular acupuncture with electrical stimulation (AE, n = 76) or without (AA, n = 37) electrical stimulation at an alternating frequency of 2/100 Hz or a sham AE with metal plates instead of needles and no electrical stimulation, no-needle (NN, n = 36) at the AA points 1 (tooth), 55 (Shen men) and 84 (mouth) during the entire study period. Regularly rated pain intensity (5-point verbal rating scale), consumption of acetaminophen 500-mg tablets and additional rescue medication with 500-mg mefenamic acid were assessed.
- The median fraction of time when pain was rated as moderate or worse (upper and lower quartile): AE: 33 % (12 %, 64 %), AA: 22 % (6 %, 56 %), NN: 30 % (7 %, 53 %) did not differ significantly among the treatment groups. There were no significant differences in mean number of acetaminophen 500-mg tablets (range): AE: 5.2 (0 to 12), AA: 4.6 (0 to 11), NN: 5.4 (0 to 10) or percentage of patients requiring additional mefenamic acid: AE: 19 %, AA: 18 %, NN: 19 %. The authors concluded that neither AE nor AA alone reduce either pain intensity or analgesic consumption in a molar tooth extraction model of acute pain.
- Wang (2007) reported the successful treatment of a patient with post-herpetic neuralgia (PHN) using traditional pharmacology in combination with acupuncture. A 13-year old girl developed PHN following a severe attack of varicella zoster. Despite a 1-week course of intravenous acyclovir initiated at the onset of symptoms, the patient developed persistent left facial pain and constant nausea after lesions were healed. A comprehensive pain treatment regimen, consisting of a stellate ganglia block, medications, transcutaneous electrical nerve stimulation and hypnosis, was administered, but the patient did not gain any incremental pain relief. The acupuncture service was consulted to provide assistance with this patient's pain management. A combination

of body and auricular acupuncture as well as related techniques, including acupressure and transcutaneous acupoint electrical stimulation, was added to the pain treatment regimen.

- After 10 complementary acupuncture treatments over a 2-month period, the patient's nausea disappeared. Her left facial pain continued to decline from a maximum of 10 to 0 as assessed by a VAS over a period of 4 months following self-administered treatments of acupressure and transcutaneous acupoint electrical stimulation. The patient was then gradually weaned off all her medications and the complementary acupuncture treatment. She was discharged from the pediatric pain clinic after 5 months of the combined therapy. The author concluded that acupuncture and its related techniques may be an effective adjunctive treatment for symptoms associated with PHN and deserved further study.
- Holzer et al (2011) examined the effects of electrical auricular acupuncture (AA) on post-operative pain in patients undergoing laparoscopy with an emphasis on patient-blinding and the exclusion of therapist-patient interactions. With institutional review board approval and written informed consent, these investigators included 40 female patients undergoing laparoscopy. Patients were randomly assigned to receive AA (shen men, thalamus and 1 segmental organ-specific point) or electrodes only and an electrical stimulation device. All patients received this intervention under general anesthesia guaranteeing patient blinding and excluding therapist-patient interactions. Needles and devices were removed 72 hours post-operatively. Post-operatively, patients received 1,000-mg paracetamol every 6 hours. Additional piritramide was given on demand. A blinded observer obtained the VAS scores at 0, 2, 24, 48, and 72 hours as well as the post-operatively administered doses of piritramide.
- There was no difference in VAS scores or the consumption of piritramide during the first 72 hours post-operatively between groups (acupuncture versus placebo: 2.32 [1.40 to 3.25] versus 2.62 [1.89 to 3.36] average pain on VAS 0-10; 15.3 [12.0 to 18.6] mg versus 13.9 [10.5 to 17.3] mg piritramide). Values are expressed as mean CI. The authors concluded that the findings of this study showed no reduction in post-operative pain or an opioid sparing effect of auricular acupuncture in women undergoing laparoscopic procedures. Because the authors emphasized blinding of the patients and the exclusion of therapist-patient interactions, this study suggested that electrical auricular acupuncture has no effect on post-operative pain.
- In a double-blind, randomized, placebo-controlled, repeated-measures trial, Fary and colleagues (2011) examined the effectiveness of sub-sensory, pulsed electrical stimulation (PES) in the symptomatic management of osteoarthritis (OA) of the knee. A total of 70 participants with clinical and radiographically diagnosed OA of the knee were randomized to either PES or placebo. The primary outcome was change in pain score over 26 weeks measured on a 100-mm VAS. Other measures included pain on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), function on the WOMAC, patient's global assessment of disease activity (on a 100-mm VAS), joint stiffness on the WOMAC, quality of life on the Medical Outcomes SF-36 health survey, physical activity (using the Human Activity Profile and an accelerometer), and global perceived effect (on an 11-point scale). Thirty-four participants were randomized to PES and 36 to placebo.
- Intent-to-treat analysis showed a statistically significant improvement in VAS pain score over 26 weeks in both groups, but no difference between groups (mean change difference 0.9 mm [95 % CI: -11.7 to 13.4]). Similarly, there were no differences between groups for changes in WOMAC pain, function, and stiffness scores (-5.6 [95 % CI: -14.9 to 3.6], -1.9 [95 % CI: -9.7 to 5.9], and 3.7 [95 % CI: -6.0 to 13.5], respectively), SF-36 physical and mental component summary scores (1.7 [95 % CI: -1.5 to 4.8] and 1.2 [95 % CI: -2.9 to 5.4], respectively), patient's global assessment of disease activity (-2.8 [95 % CI: -13.9 to 8.4]), or activity measures; 56 % of the PES-treated group achieved a clinically relevant 20-mm improvement in VAS pain score at 26 weeks compared with 44 % of controls (12 % [95 % CI: -11.5 to 33 %]).
- The authors concluded that in this sample of subjects with mild-to-moderate symptoms and moderate-to-severe radiographic OA of the knee, 26 weeks of PES was no more effective than placebo.

- The Neurolumen is a portable machine that consists of a control unit, 4 wrap assemblies and a battery charger. Each wrap contains 2 laser diodes, 4 light emitting diodes and 1 or 2 electrolytic nerve stimulation gel pads. Once the wraps are in place, the control unit provides up to 30 mins of simultaneous TENS, low-level laser (LLLT) and light-emitting diode (LED) therapy.
<http://www.neurolumen.com/products.php>.
- However, there is a lack of evidence regarding the effectiveness of the Neurolumen device for the treatment of Morton's neuroma or any other indications. An UpToDate review on "on Peripheral Nerve Tumors" (Gilchrist and Donahue, 2013) states that "Morton neuroma is a subject of controversy regarding its nomenclature, pathology, and appropriate treatment. Abnormalities ascribed to Morton neuroma are typically located between the metatarsals of the third and fourth toes or at the bifurcation of the fourth plantar digital nerve. The lesions look like a traumatic neuroma grossly, and are comprised of degenerated and/or demyelinated axons, vascular hyalinization, and fibrosis. Clinical manifestations can include pain and tenderness, but similar lesions are common in patients who are asymptomatic.
- Surgical removal is advocated by some authors for those who fail conservative measures, but data are limited regarding the effectiveness of surgical and nonsurgical interventions for Morton neuroma". Furthermore, an UpToDate review on "Overview of running injuries of the lower extremity (Callahan, 2013) does not mention the use of electrical stimulation or laser therapy as therapeutic options for Morton's neuroma.
- According to the FixPain website, the NIP Procedure refers to "Non-Invasive, or No-Incision Pain" Procedure. It is FDA-cleared/certified for various types of chronic pain (arthritis, cancer pain, cervical pain, fibromyalgia, joint pain, low back pain, migraines, post-operative pain, and sciatica) and other conditions (e.g., anxiety, depression and insomnia). The microchip NIP Procedure device is placed behind the ear of the patient, the acupuncture in corresponding points and the pulses are transmitted through the stimulating needle. With the help of the NIP Procedure" device, the patients are receiving continuous treatment for 4 to 5 days. It is recommended that therapies be applied for up to 9 weeks. <http://www.fixpain.com/>.
- However, there is a lack of evidence regarding the effectiveness of the NIP Procedure device for the treatment of chronic pain or any other indications.
- Electro-Analgesia Treatment (EAT) has been described as nerve block injections followed by electrical stimulation administered with the Synaptic device, and has been used as a treatment for diabetic peripheral neuropathy. The combination of nerve block therapy and electrical stimulation is referred to as Electro-Analgesia Treatment or EAT. The manufacturer states that the Synaptic 4000 treatment is controlled by the patient using a joystick.
- According to the manufacturer, electrical stimulation with the Synaptic device is different from other forms of electrical stimulation: "The Synaptic technology is unique and stands apart from all other electrical neuro-stimulation devices such as TENS, EMS, FES, sacral nerve stimulation (SNS), vagus nerve stimulation (VNS), deep brain stimulation (DBS), spinal cord stimulation (SCS) and cochlear and ocular implants." The manufacturer explains: "The frequency range is from 40,000 to 400 Hertz. Conventional modalities have a frequency range of only 500-180 Hertz and begin their activity at the low end of the range increasing to their maximum as controls are elevated. In contrast, Synaptic begins its frequency sweep at the maximum (40,000 Hertz) and as the remote is advanced the frequency decreases to the minimum (400 Hertz). This cycle may be repeated during each of the ten intensity levels."
- The manufacturer states that the waveform of the Synaptic is also unique. "Also protected are the A-waveform, the unique mechanism for SEA energy delivery as well as the method of patient-controlled treatment using a joystick. The waveform developed for SEA technology mimics a biological process. It simulates the action potential responsible for producing electrical activity in the neuron using a fast rise time and a slow decay, reproducing the action potential in humans."
- There are a lack of peer-reviewed published studies of Electro-Analgesia Treatment or of the Synaptic electrical stimulation device.
- **Appendix**
- *TENS Unit Supplies*

- A 4-lead TENS unit may be used with either 2 leads or 4 leads, depending on the characteristics of the member's pain. If it is ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the member's needs.
- If 2 TENS leads are medically necessary, then a maximum of 1 unit of a TENS supply allowance (HCPCS Code A4595) would be considered medically necessary per month; if 4 TENS leads are necessary, a maximum of 2 units per month would be considered medically necessary. If the use of the TENS unit is less than daily, medical necessity of the TENS supply allowance is reduced proportionally. Note: A TENS supply allowance (HCPCS code A4595) includes electrodes (any type), conductive paste or gel (if needed, depending on the type of electrode), tape or other adhesive (if needed, depending on the type of electrode), adhesive remover, skin preparation materials, batteries (9 volt or AA, single use or rechargeable), and a battery charger (if rechargeable batteries are used).
- Replacement of lead wires more often than every 12 months is rarely medically necessary.

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Footnotes

[A] The physician ordering the TENS unit must be the attending physician or a consulting physician for the disease or condition resulting in the need for the TENS unit. If the TENS unit produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation (PENS) may be indicated.

[B] The physician's records must document a reevaluation of the member at the end of the trial period, must indicate how often the member used the TENS unit, the typical duration of use each time, and the results.

[C] FES devices such as the FES Power Trainer, ERGYS, REGYS, NeuroEDUCATOR, STimMaster Galaxy, RT300 motorized FES ergometer, and SpectraSTIM are all considered to be exercise equipment. Most plans exclude coverage of exercise equipment; please check benefit plan descriptions for details

Codes

CPT® : 64550, 64565, 64568, 64575, 64580, 64590, 64595, 95860, 95861, 95863, 95864, 95865, 95866, 95867, 95868, 95869, 95870, 95872, 95937, 97014, 97032, E0731, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688

HCPCS: E0720, E0730, S8930

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