CIGNA HEALTHCARE COVERAGE POSITION

Revised Date 8/15/2007
Original Effective Date 9/15/2004
Coverage Position Number 0160

Subject **Electrical Stimulators**

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INSTRUCTIONS FOR USE

*Coverage Positions are intended to supplement certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Positions are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Position. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Positions. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Positions and; 4) the specific facts of the particular situation. Coverage Positions relate exclusively to the administration of health benefit plans. Coverage Positions are not recommendations for treatment and should never be used as treatment guidelines.*

Coverage Position

Coverage for electrical stimulation devices is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for electrical stimulation devices is available, the following conditions of coverage apply.

CIGNA HealthCare covers neuromuscular electrical stimulation (NMES) as medically necessary when used as one component of a comprehensive rehabilitation program for the treatment of disuse atrophy when the nerve supply to the atrophied muscle is intact.

CIGNA HealthCare covers the use of a transcutaneous electrical nerve stimulator (TENS) as medically necessary for the relief of chronic pain when there is failure of at least a 30-day trial of conventional medical management including medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], acetaminophen) and physical therapy.

CIGNA HealthCare covers a conductive garment as medically necessary when used in conjunction with medically necessary NMES or TENS for ANY of the following clinical situations:

- The use of conventional electrodes, tapes or lead wires is not feasible either because the individual has a large area requiring treatment or a large number of sites requiring stimulation.
- The site(s) requiring stimulation (i.e., back) is/are difficult to reach with conventional electrodes, tapes or lead wires.
- A co-existing medical condition (e.g., skin problems) precludes the use of conventional electrodes, tapes or lead wires.

CIGNA HealthCare does not cover the use of any of the following electrical stimulation devices, because each is considered experimental, investigational, or unproven for the treatment of any condition (this list may not be all-inclusive):

- bioelectric nerve block (electroceutical therapy)
- electrical bladder stimulation
- H-WAVE electrical stimulator
- high-voltage galvanic stimulator (HVG)
- interferential therapy for any indication, including pain and bone fractures
- MICROCURRENT electrical nerve stimulation (MENS), including frequency-specific microcurrent (FSM)
- percutaneous electrical nerve stimulation (PENS)
- percutaneous neuromodulation therapy (PNT)
- peripheral tibial nerve stimulation (PTNS)

General Background

Electrical stimulator devices may provide direct alternating, pulsating or pulsed waveform forms of energy. The devices are used to exercise muscles by stimulation through electrodes placed on the skin. Electrical stimulators are also said to be used to demonstrate a muscular response to stimulation of a nerve, relieve pain, cause contraction of muscles, relieve incontinence, and provide test measurements. Electrodes for such devices may be implanted, indwelling, transcutaneous (needles) or surface. Electrical stimulators may have controls to set the pulse length, pulse repetition frequency, pulse amplitude, and triggering modes. Stimulators should be battery operated or fully electrically isolated.

Neuromuscular Electrical Stimulators (NMES)
NMES is characterized by low-voltage stimulation targeted to stimulate motor nerves to cause a muscle contraction. Contraction/relaxation of muscles has been used in an effort to treat a variety of musculoskeletal and vascular conditions. NMES has been favorably evaluated in the treatment of disuse atrophy where the nerve supply to the muscle is intact. NMES differs from transcutaneous electrical nerve stimulator (TENS) in that it attempts, through multiple channels, to stimulate motor nerves and alternately causes contraction and relaxation of muscles, while TENS is designed to stimulate sensory nerve endings to help decrease pain. NMES is generally considered medically necessary for the treatment of disuse atrophy where the nerve supply to the muscle is intact.

U.S. Food and Drug Administration (FDA): Neuromuscular electrical stimulators are regulated by the U.S. Food and Drug Administration (FDA) as Class II devices, and hundreds of these devices have been approved via the FDA 510(k) process.

Literature Review: Bax et al. (2005) performed a systematic review of randomized controlled trials (RCTs) that evaluated the effectiveness of NMES. Thirty-five RCTs were included. The trials were separated into two groups: trials that used patients with unimpaired quadriceps femoris muscles and trials that used post-injury or postoperative subjects (impaired quadriceps femoris muscles). NMES was compared to no exercise and volitional exercise in each group. The data suggests that, in both the unimpaired and impaired groups, NMES was more effective than no exercise and more effective than

volitional exercises when used during a period of immobilization, especially under a cast. Volitional exercises, however, were found to be equal to or more effective in all other cases.

Lieber et al. (1996) compared NMES to voluntary muscle contraction in an RCT of 40 men and women ages 15–44 following knee surgery. Each subject was randomly assigned to either an electrical stimulation group or a voluntary contraction group. The subjects received treatment for 30 minutes a day for five weeks. No significant difference was found between the groups in terms of maximum voluntary knee-extension torque ($p<0.04$). These data suggest that neuromuscular electrical stimulation and voluntary muscle contraction treatments, when performed at the same intensity, are equally effective in strengthening skeletal muscle that has been weakened by surgical repair of the anterior cruciate ligament.

Lake (1992) reports in a comprehensive review that NMES has been used for muscle strengthening, maintenance of muscle mass and strength during prolonged periods of immobilization, selective muscle retraining, and the control of edema. A wide variety of stimulators, including the burst-modulated alternating current twin-spiked monophasic pulsed current and biphasic pulsed current stimulators, have been used to produce these effects. Several investigators have reported increased isometric muscle strength in both NMES-stimulated and exercise-trained healthy, young adults when compared to unexercised controls. The authors conclude that there is evidence that NMES can improve functional performance in a variety of strength tasks. The authors have suggested two mechanisms explain the training effects seen with NMES. The first mechanism proposes that augmentation of muscle strength with NMES occurs in a similar manner to augmentation of muscle strength with voluntary exercise. This mechanism would require NMES strengthening protocols to follow standard strengthening protocols which call for a low number of repetitions with high external loads and a high intensity of muscle contraction. The second mechanism proposes that the muscle strengthening seen following NMES training results from a reversal of voluntary recruitment order with a selective augmentation of type II muscle fibers. Because type II fibers have a higher specific force than type I fibers, selective augmentation of type II muscle fibers will increase the overall strength of the muscle. The use of neuromuscular electrical stimulation to prevent muscle atrophy associated with prolonged knee immobilization following ligament reconstruction surgery or injury has been extensively studied. NMES has been shown to be effective in preventing the decreases in muscle strength, muscle mass and the oxidative capacity of thigh muscles following knee immobilization. In all but one of the studies, NMES was shown to be superior in preventing the atrophic changes of knee immobilization when compared to no exercise, isometric exercise of the quadriceps femoral muscle group, isometric co-contraction of both the hamstrings and quadriceps femoral muscle groups, and combined NMES isometric exercise. It has also been reported that NMES applied to the thigh musculature during knee immobilization improves the performance on functional tasks.

Morrisey et al. (1985) report in a case comparison that mobilization of the knee after anterior cruciate ligament (ACL) reconstruction results in marked thigh atrophy and decrease in quadriceps strength that may prolong the rehabilitation program of the patient. Fifteen male volunteers undergoing ACL reconstruction were divided into two groups: stimulation (during immobilization) and nonstimulation. Measurements of thigh circumference and isometric quadriceps strength were tested preoperatively, immediately after cessation of cast immobilization (six weeks), and at nine and 12 weeks postoperatively. The changes in circumference and strength between the first preoperative test and all subsequent tests were compared for statistical significance (student's t-test, $p<0.5$) between the two groups. The decrease in quadriceps strength of the stimulation group during immobilization was significantly less than that of the nonstimulation group, although later differences between the two groups were not significant. There were no significant differences in thigh atrophy between the two groups. The authors conclude that isometric quadriceps torque decreases resulting from immobilization can be significantly lessened by application of electrical stimulation during immobilization.

Gould et al. (1983) reported a comparison study to determine the effectiveness of NMES by a portable device in preventing atrophy. Ten patients treated by open meniscectomy and given the usual isometric training were matched to 10 patients in whom electrostimulation, consisting of a strong five-second sustained muscular contraction about 400 times/day, was used for two weeks. Muscular strength and leg circumference were measured before surgery and four weeks after surgery. The authors report that the electrically stimulated group had a significantly smaller loss of muscle volume and muscle strength, were

able to walk earlier without crutches, had a greater range of knee motion, had much less postoperative knee swelling, and used significantly less pain medication. The authors believe that NMES may prevent muscle atrophy due to immobilization, thereby shortening rehabilitation time.

Although the evidence is limited, the use of NMES for the treatment of disuse atrophy in patients where the nerve supply to the muscle is intact is considered standard of care within the medical community when included as part of a comprehensive rehabilitation program. Protocols in the literature recommend that no more than two hours of NMES treatment within a 24-hour period are medically necessary. The treatment plan should be reevaluated every 30 days.

There is insufficient evidence to support the safety or efficacy of NMES in the treatment of rheumatoid arthritis; preventing and/or treating post-stroke pain; toning, strengthening and firming of abdominal muscles; treatment of fecal incontinence; low back pain; Bell's palsy; sensory stimulation for coma patients; motor disorders; cerebral palsy or treatment of chronic ulcers or other conditions.

Transcutaneous Electrical Nerve Stimulation (TENS)
TENS devices consist of an electronic stimulus generator that transmits pulses of various configurations to electrodes on the skin for the purpose of pain management. The mechanism of action is unknown. It has been postulated that the electrical pulses may block transmission of pain-nerve fibers or may stimulate release of endorphins or of serotonin, an endogenous substance that can reduce perception of pain. TENS has been used for a number of applications, including acute and chronic pain, postoperative pain, obstetrical pain and pain associated with medical procedures. It has been shown that TENS may be effective in alleviating pain and reducing analgesic medications following some surgical procedures (Agency for Healthcare Policy and Research [AHCPR], 1992).

Literature Review: Bjordal et al. (2007) conducted a systematic review of the short-term treatment efficacy of physical agents in osteoarthritis of the knee (OAK). Thirty-six randomized controlled trials were included. Eleven trials were performed with TENS (n=425), eight with low level laser therapy (LLLT) (n=343), four trials with manual acupuncture, three with electro-acupuncture (EA), one trial with ultrasound therapy, seven with pulsed electromagnetic fields (PEMF), and two with static magnets. According to the study, use of TENS resulted in statistically significant short-term pain relief with clinically relevant effects 1–2 months after the end of treatment. This study suggests that TENS can be useful as an adjunct to pain management in patients with OAK.

Khadilkar et al. (2005) conducted a systematic review of the evidence on TENS for the management of chronic low back pain (LBP). Two RCTs were included in this review. The studies differed in terms of design, methodologic quality, inclusion and exclusion criteria, characteristics of TENS application, treatment schedule, and measured outcomes. TENS produced significantly greater pain relief than the placebo control in one RCT. However, in the other RCT, no statistically significant differences between treatment and control groups were shown for multiple outcome measures. The authors found the evidence to be limited and inconsistent. It was concluded that larger, multicenter RCTs are needed to better define the role of TENS as an isolated intervention in the management of chronic LBP.

McQuay et al. (1999) conducted a systematic review of the evidence regarding the effectiveness of outpatient services and treatments for chronic pain control. Searches of databases and journals identified over 15,000 randomized studies with pain as an outcome. Over 150 systematic reviews relevant to chronic pain treatment were identified and their quality assessed using a simple scoring system. Systematic reviews conducted for the report were based mainly on randomized trials. The sample groups included men, women and children. The outcome measures were pain intensity, pain relief, adverse effects and costs. Physical interventions included TENS. The authors found that TENS has been shown to be ineffective in postoperative and labor pain. In chronic pain, there is evidence that TENS effectiveness increases slowly and that large doses need to be used.

Chabel et al. (1998) conducted a retrospective review to assess a variety of treatment outcomes in long-term users of TENS who suffer from chronic pain. Key components of the study examined the effects of long-term TENS therapy on pain-related medications and physical/occupational therapy (PT/OT) use. From a population of chronic pain patients (CPPs) who acquired a TENS device for pain management, a randomly selected sample of 376 patients who used TENS were interviewed by telephone by an

independent research firm. The survey assessed a variety of outcome variables, including changes in medication use, number of pain-related medications, and use of PT/OT prior to TENS and after a minimum six months of TENS treatment. The data were subjected to a paired t-test analysis. A cost simulation model was then applied to the medication and PT/OT data. The mean duration of pain, for which TENS was prescribed, was 40–60 months. As compared to the period prior to TENS use, the long-term TENS user group reported a statistically significant reduction in the following types of pain medications: opiate analgesics, tranquilizers, muscle relaxants, nonsteroidal anti-inflammatory drugs (NSAIDs), and steroids. PT/OT use was also significantly reduced. Cost simulations of pain medications and PT/OT are presented. The authors concluded that long-term use of TENS is associated with a significant reduction in the utilization of pain medication and PT/OT. In this study population, cost simulations of medication and PT/OT indicate that with long-term TENS use, costs can be reduced up to 55% for medications and up to 69% for PT/OT. The authors believe that the potential for TENS associated improvement combined with reduced medication related complications and costs are important points that clinicians should consider when constructing a treatment plan for chronic pain patients.

The Canadian Coordinating Office for Health Technology Assessment (1995) 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.

Carroll et al. (2005) reported in a Cochrane systematic review that the results were inconclusive; the published trials did not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor did they answer questions about long-term effectiveness. Large multi-centre randomized controlled trials of TENS in chronic pain are urgently needed.

The peer-reviewed scientific literature has not established the safety and efficacy of TENS for the treatment of: post-traumatic acute pain, pain associated with childbirth, dental pain, fracture and healing pain, back pain, myofascial dysfunction pain, chronic leg ulcers, low back pain during labor, unstable angina, osteoarthritis of the knee, placental insufficiency, or knee arthroplasty (Cochrane, 2004). The efficacy of TENS has not been established in the treatment of: nausea and vomiting of pregnancy, motion sickness, or chemotherapy-induced pain (Hayes, 2003). The available peer-reviewed literature is inconclusive as to the safety and efficacy of TENS for the treatment of tinnitus. Given the inconclusive outcome data of the various studies in the use of TENS, any analysis could be misleading. There is some anecdotal information that TENS as an adjuvant therapy for chronic pain may allow for some reduction in chronic pain levels.

There is limited evidence in the peer-reviewed literature to support the use of TENS for the secondary treatment of patients with chronic pain if conventional therapy has failed and, because TENS has been used to treat this condition before evidence-based medicine became available, it is considered as a standard of care by the community.

Conductive Garments

Conductive garments are fabric electrodes used between electrical stimulators and a patient's skin for the delivery of electrical stimulation (FDA, 2002). They are proposed for use in patients with chronic pain who have large areas or a large numbers of sites to be stimulated or the frequency is such that it is not feasible to use conventional electrodes, tapes, or lead wires; sites requiring stimulation that are not accessible by the patient with conventional electrodes, tapes or lead wires (i.e., back); medical conditions (e.g., skin problems) that preclude the use of conventional electrodes, tapes or lead wires; and the need for electrical stimulation beneath a cast (Noridian, 2007).

In September 2002, the FDA issued 510(k) premarket approval to AG Garments (San Diego, CA) for the AG Garments Conductive Electrodes as an equivalent to predicate devices or to devices that do not require a premarket approval application. The electrodes are intended for use as reusable (by a single patient), cutaneous, flexible, conductive garment/fabric electrodes for interface between electrical stimulators and a patient's skin for the delivery of electrical stimulation (FDA, 2002).

Bioelectric Nerve Block (Electroceutical Therapy)

Bioelectric therapy, also known as noninvasive neuron-blockade devices, electroceutical neuron-blockade devices and bioelectric treatment systems, is proposed as a treatment for acute pain and chronic pain (e.g., back pain, diabetic pain, joint pain, fibromyalgia, headache, and reflex sympathetic dystrophy). Electroceutical treatments use much higher electrical frequencies than TENS units (ranging from one to 20,000 Hz compared to 0.5 to 100 Hz used in TENS). Electrical current is altered via special step-down transformers into bioelectric impulses, which are designed to mimic the human bioelectric system. The proper electroceutical class, dosage, regimen duration and anatomical placement of electrodes are determined by the individual patient's diagnosis. Electroceutical therapy is claimed to have resulted in significant relief of pain and elimination or pain medication in patients.

There is a lack of peer-reviewed scientific evidence to substantiate the efficacy of bioelectric therapy. 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.

Electrical Bladder Stimulation For The Treatment Of Urinary Incontinence
Electrical stimulation is proposed as a treatment to modify bladder and sphincter behavior in decreasing urge, stress and mixed forms of urinary incontinence. There are three primary types of incontinence:

- stress incontinence, caused by a weakening of the pelvic floor muscles
- urge incontinence, caused by the urgent need to void caused by a sudden bladder contraction
- overflow incontinence, caused by the bladder becoming too full yet unable to be emptied, usually caused by obstruction or injury

Pelvic Floor Electrical Stimulation (PFES): Although the exact mechanism is not fully understood, it is postulated that electrical bladder stimulation activates the pudendal nerve, causing contraction of smooth, striated urethral muscles and striated pelvic floor muscles. The electrical stimulation is transmitted via vaginal or anal electrodes intending to improve urethral closure and strengthen the pelvic floor muscles. The data are insufficient to draw conclusions as to the safety and efficacy of electrical bladder stimulation (Hayes, 2003).

U.S. Food and Drug Administration (FDA): All devices with surface electrodes used for bladder stimulation are Class II devices. FDA 510(k)-approved, nonimplantable electrical stimulators include the following:

- Detrusan® 500 (Innovamed USA, Inc., Lehigh Acres, FL)
- Pathway™ CTS 2000 (Prometheus Group, Duxbury, MA)
- Urostym™ (Laborie Medical Tech Corp., Williston, VT)
- Elpha® 2000 (Dan Med, Inc., Boulder, CO).

Literature Review: Goode et al. (2003) studied the effect of behavioral training with and without PFES on stress incontinence in 200 women in an RCT. Patients were randomly assigned to eight weeks (four visits) of behavioral training; eight weeks (four visits) of behavioral training plus home PFES; or eight weeks of self-administered behavioral treatment using a self-help booklet. Significant improvement was seen in all groups on the incontinence impact questionnaire, with no between-group differences. Treatment with PFES did not increase effectiveness of a comprehensive behavioral program for women with stress incontinence. There is no current consensus regarding the efficacy of bladder stimulation. Clear patient selection criteria are not available.

The California Technology Assessment Forum (CTAF) reviewed the evidence on the use of PFES as a treatment for urinary incontinence in women. The report evaluated nine trials that compared electrical stimulation to placebo. Of these studies, three found statistically significant results in favor of PFES. However, because of the variations within the studies, conclusions could not be drawn as to the efficacy of this intervention. The author found insufficient evidence to conclude that PFES is as beneficial as behavioral or pharmacological therapies (CTAF, 2004).

A Hayes review of the literature regarding the effect of PFES with anal or vaginal electrodes found the evidence to be conflicting. Some RCTs reported a beneficial effect for stress incontinence compared to

sham treatment, while others reported minimal or no effect. There is less evidence regarding the efficacy of anal and vaginal electrical stimulation for urge and mixed urinary incontinence or postprostatectomy incontinence. In addition, optimal stimulation protocols have not been defined, and long-term effects are unknown (Hayes, 2006).

Professional Societies/Organizations: The American Urological Association (AUA) examined the scientific evidence regarding electrical stimulation for urinary incontinence. There was not a strong consensus regarding the effectiveness of vaginal, suprapubic and/or anal electrical stimulation for stress, urge or mixed incontinence. Further randomized trials need to be conducted, including a comparative study of electrical stimulation versus behavioral modification (AUA, 2000).

There is insufficient peer-reviewed scientific literature to support the use of electrical bladder stimulation for the treatment of urinary incontinence.

Peripheral Tibial Nerve Stimulation (PTNS): Electrical stimulation of the tibial nerve has also been proposed as a potential treatment for urinary incontinence. The posterior tibial nerve is a mixed sensory and motor nerve containing fibers originating from the lumbar and sacral areas of the spine. The sacral nerves modulate the somatic and autonomic nerve supply to the bladder and urinary sphincter. PTNS involves neuromodulation of the sacral nerve which is thought to inhibit bladder instability.

U.S. Food and Drug Administration (FDA): The Urgent® PC Neuromodulation System (Uroplasty, Inc., Minneapolis, MN) was granted marketing approval by the FDA via the 510(k) process on October 17, 2005, because it is considered to be substantially equivalent to another device already on the market. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the Urgent® PC Neuromodulation System prior to marketing the device. The 510(k) summary stated that this device is substantially equivalent to the UroSurge® Percutaneous Stoller Afferent Nerve Stimulator (SANS™) Device. The Urgent PC stimulation system delivers an electrical current to the sacral nerve from the tibial nerve via a needle electrode. According to the FDA, the device is intended to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence.

Literature Review: The majority of studies identified in the literature that addressed PTNS were cohort studies and case series with small study populations and short-term follow-up. Patient selection criteria and treatment protocol were also not standardized. Govier et al. (2001) conducted a prospective multicenter clinical trial to determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment of refractive overactive bladder (OAB) and/or pelvic floor dysfunction. Patients were treated with 12 weekly SANS sessions. Urodynamic studies, detailed voiding diaries, quality of life surveys, and incontinence impact questionnaires were completed before, during and after the study. The 12-week study was completed by 47 of 53 patients. A total of 71% of patients were reported to be treatment successes by the investigators and were started on long-term treatment. On average, patients noticed a 25% reduction in mean daytime and 21% reduction in mean nighttime voiding frequencies ($p<0.05$). Urge incontinence was reduced by an average of 35% ($p<0.05$). Statistically significant improvements were noted in selective pain and quality of life indexes. No significant adverse events related to treatment were noted in any patients.

Vandoninck et al. (2003) reported on 90 consecutive OAB patients treated with PTNS. Patients underwent 12 PTNS sessions. The primary outcome measure was a decrease in number of urinary leakage episodes of 50% or more per 24 hours. Pre- and post-treatment urodynamic data were available from 46 participants. The objective and subjective success rates were reported to be 56% and 64%, respectively. Frequency/volume chart data and quality of life scores improved significantly ($p<0.01$). Detrusor instabilities (DI) could be eliminated in only a few cases. It was noted that patients without DI at baseline were 1.7 times more prone to respond to PTNS. It was concluded that patients without DI or with late-onset DI seemed to be the best candidates for PTNS. According to the authors, PTNS is an emerging therapy that requires further research, assessing predictive factors and optimal stimulation parameters.

Karademir et al. (2005) compared outcomes in patients after treatment with SANS alone (n=21) or SANS plus a low-dose anticholinergic medication (n=22). SANS was applied for 60 minutes once weekly for a total of eight weeks. The treatment response rate was 61.6% for the SANS group and 83.2% in the SANS

plus medication group. In both groups, the best symptomatic improvements were obtained in patients with urge incontinence. The authors concluded that combination with a low-dose anticholinergic increases the success rate of SANS without causing significant side effects.

In a prospective observational study, Nuhoglu et al. (2006) investigated the efficacy of the SANS device in 35 patients with OAB deemed unresponsive to pharmacotherapy. Treatment was given once a week for 30 minutes for a total of 10 weeks. Quality of life questionnaires, three-day voiding diaries, and cystometry were completed before and after SANS treatment and at one-year follow-up. Early success rate was found to be 54%, with improvements seen in voiding diary parameters, urodynamic parameters and quality of life scores. Efficacy was maintained at one year in only 23% of 32 patients. It was concluded that SANS treatment had a positive short-term effect in patients with resistant OAB; however, efficacy decreases in about three months. The investigators proposed that SANS treatment should be repeated at regular intervals to prevent relapses but stated that further studies would be required to support this hypothesis.

Currently, there is insufficient peer-reviewed data to support the efficacy of PTNS.

H-Wave Electrical Stimulator
H-WAVE electrical stimulator generates a biphasic, exponentially decaying waveform with pulse-wide widths. The output parameters are distinct from those of TENS modalities. H-WAVE is classified as a powered muscle stimulator. At a low-wave setting, muscle contractions are achieved through skin-applied, self-adhesive electrodes. H-WAVE produces rhythmic muscle contractions. Ongoing muscle contractions increase local circulation and lymphatic drainage. The manufacturer states that the high frequency manages intractable pain, the goals being to break the pain cycle and to obtain lasting and cumulative pain relief. The large pulse width theoretically enables contraction in the muscle for extended periods at a low fatigue rate with increased patient circulation. While physiatrists, chiropractors, or podiatrists may perform H-wave stimulation, H-wave devices are suggested for home use. H-wave stimulation has been used in the treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy. H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography.

U.S. Food and Drug Administration (FDA): H-WAVE Muscle Stimulator (Electronic Waveform Laboratory, Inc., Huntington Beach, CA) was FDA 510(k) approved as a class II device in 1997.

Literature Review: Blum et al. (2006) reported on an observational study in which 6774 patients with chronic soft tissue injury or neuropathic pain evaluated their response to the H-Wave device by answering a 10-item questionnaire. The H-Wave Customer Service Questionairre (HCSQ) measured each patient's subjective assessment of the device's effectiveness regarding decreased or eliminated need for pain medication, increased functioning and activity, and 25% or greater overall improvement. The patients also rated their overall improvement on a 10-unit visual analog scale ranging from 0%–100%. According to the study, 75% of the participants reported reduced or eliminated need for pain medications (P<.0001); 79% reported improved functional capacity or activity (P<.0001); and 78% reported 25% or greater overall improvement (P<.0001). The results of this study suggest the H-Wave device may provide an alternative to pharmacological treatment of chronic soft tissue injury and neuropathic pain. However, limitations of this study include the use of self-reported data and lack of randomization and control.

Clinical trials of H-wave stimulation therapy in the peer-reviewed literature that use random assignment and placebo control are limited to one group of investigators. Kumar and Marshall compared active H-wave electrical stimulation with sham stimulation for treatment of diabetic peripheral neuropathy.

Kumar et al. (1997) reported RCT (n=31) patients with type 2 diabetes and painful peripheral neuropathy in both lower extremities lasting at least two months. Patients were excluded if they had vascular insufficiency of the legs or feet, or specified cardiac conditions. Patients were randomly assigned to the active group (n=18) or the sham group (n=13). Both groups were instructed to use their devices 30 minutes daily for four weeks. The device used in the sham group had inactive electrodes. Outcomes were assessed using a pain grading scale ranging from 0–5. The authors concluded that both groups experienced significant declines in pain, and the post-treatment mean grade for the active group was

significantly lower than the mean grade for the sham group. This study did not state whether patients and/or investigators were blinded and did not state whether any patients withdrew from the study.

Kumar et al. (1998) compared active H-wave electrical stimulation to sham stimulation among patients treated initially with tricyclic antidepressants. The authors enrolled 26 patients with type 2 diabetes and painful peripheral neuropathy persisting for two months or more. Exclusion criteria were similar to those used in the earlier study. Amitriptyline was administered for four weeks initially, and those who had a partial response or no response were later randomized to the two groups. After excluding three amitriptyline responders, the active stimulation group included 14 patients, and the sham stimulation included nine patients. Sham devices had inactive output terminals. Stimulation therapy lasted 12 weeks. As in the earlier study, mean pain grade in both groups improved significantly, but the difference between groups after treatment significantly favored active H-wave stimulation. Results on an analog scale were similar. It is unclear if patients were blinded to the type of device, and the report does not note whether withdrawals from the study occurred.

While the two small controlled trials provide suggestive evidence, their results are insufficient to permit conclusions about the effectiveness of H-wave electrical stimulation for diabetic neuropathy. Additional sham-controlled studies are needed from other investigators, preferably studies that are clearly blinded, specify the handling of any withdrawals, and provide long-term follow-up data.

High Voltage Galvanic Stimulation (HVG)
Galvanic stimulation is characterized by high voltage, pulsed stimulation and is recommended primarily for local edema reduction through muscle pumping and polarity effect. Edema is comprised of negatively charged plasma proteins, which leak into the interstitial space. The theory of galvanic stimulation is that the high voltage stimulus applies an electrical potential which disperses the negatively charged proteins away from the edematous site, thereby helping to reduce edema.

U.S. Food and Drug Administration (FDA): High Voltage Galvanic Stimulator (Control Solutions, Inc., Northbrook, IL) was 510(k) FDA-approved as a class II device in June 2004.

Literature Review: The few studies that were identified in the literature that addressed HVG were very small randomized clinical trials (RCT) and case comparisons. There were no patient selection criteria identified nor long-term follow-up tracked.

Balogun et al. (1996) reported in an RCT that Chinese medicine, ST36 and ST37 acupuncture points, are commonly recommended to enhance peripheral blood circulation and digestive functions; however, there is little empirical data in support of the above recommendations. This study was designed to evaluate the effects of HVG of ST36 and ST37 acupuncture points on peripheral hemodynamic functions. Eleven healthy subjects (five men, six women; mean age 28 years), voluntarily participated in the study. Pulse frequency/time-frame experimental design was employed. The subjects' ST36 and ST37 acupuncture points were stimulated, at sensory threshold intensity, with HVG current using two (5 Hz and 120 Hz) different pulse frequencies. Skin temperature and hemodynamic functions (cutaneous blood flow, microvascular volume and erythrocyte velocity) between the first and second metatarsals of the subjects' dominant foot were monitored every two minutes for 10 minutes at rest, during a 20-minute HVG stimulation treatment and 10 minutes post-stimulation. The results of the repeated-measures analysis of variance revealed no significant F-ratio for pulse frequency and time,frame main effects for any of the dependent variables. The authors report that percutaneously applied HVG stimulation of ST36 and ST37 acupuncture points does not increase peripheral hemodynamic functions in asymptomatic subjects.

Balogun et al. (1993) reported an RCT that was designed to determine the effects of pulse frequency (20 pps, 45 pps, 80 pps) on subjects' voltage tolerance, delayed muscle soreness, and muscle strength gained following six weeks of HPV. Thirty healthy men (mean age 22 years) were randomly assigned to three groups. Subjects in group 1 (n=10), group 2 (n=10), and group 3 (n=10) had their right quadriceps femoris muscles electrically stimulated with a high-voltage galvanic stimulator present at pulse frequencies of 20 pps, 45 pps, and 80 pps, respectively. The left limb of each subject served as the control. For all the groups, the duty cycle of the stimulator was set at 10 seconds on and 50 seconds off during the stimulation. At each training session, the maximal tolerable voltage for each subject was monitored. Ten maximum contractions were allowed at each training session. Muscle soreness

perception was evaluated 48 hours after stimulation using a 10-point visual analog scale. Electrical stimulation was administered three times a week for six weeks. For each subject, the average voltage output and muscle soreness rating were computed at the end of each week. With a cable tensiometer, the knee extension isometric force of both limbs was evaluated before training and at the end of the second, fourth, and sixth weeks of the study and three weeks after training. The authors concluded that the results showed that the maximum voltage tolerance, muscle soreness ratings, and muscle strength gained by the three groups are not significantly ($p>.05$) different.

Mohr et al. (1985) reported a study to compare the effectiveness of HVG to isometric exercise to strengthen the quadriceps femoris muscles in 17 healthy subjects. The subjects were divided into three groups. The control group (n=6) received no exercise or stimulation. The isometric exercise group (n=5) performed 15 sessions of maximum isometric contractions, and the HPV group (n=6) engaged in 15 sessions of electrically stimulated isometric contractions. The isometric exercise group was found to have an increase in strength significantly greater ($p>.05$) than either the control or HPV group. No increase in strength was observed in either the control or electrical stimulation group. The authors concluded that HVG stimulation was not as effective as isometric exercise in increasing strength in muscle.

There is insufficient peer-reviewed data to support the efficacy of HVG at the present time.

Interferential Therapy (IF)
IF is a treatment modality that aims to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. Two medium-frequency, pulsed currents are delivered via electrodes placed on the skin over the targeted area. The superimposition or interference of these frequencies deep within the tissues produces a new low-frequency current that would otherwise be painful because of the impedance of skin and subcutaneous tissues (Palmer, et al., 1999). IF is widely used by physiotherapists, despite a lack of evidence demonstrating its superiority over other treatment modalities. It is theorized that IF prompts the body to secrete endorphins and other natural painkillers and stimulates parasympathetic nerve fibers to increase blood flow and reduce edema.

U.S. Food and Drug Administration (FDA): Interferential stimulator instruments are regulated by the FDA as Class II devices. More than 50 instruments have received 510(k) approval. A complete list of devices for IF is too extensive for inclusion in this report. The FDA-approved list includes:

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

Literature Review: Few randomized controlled studies evaluating the efficacy of IF on pain or soft tissue injury were available for review. Taylor et al. (1987) found that IF was no more effective than placebo in decreasing jaw pain or increasing vertical jaw opening. In 1987, van der Heijden et al. found that neither IF nor ultrasound was an effective adjuvant to exercise therapy in individuals with pain or restricted mobility due to localized soft tissue shoulder impairment. Hurley et al. (2001) suggested that electrode placement may have some significance among individuals treated with IF, but found no significant differences in outcomes between individuals treated with IF plus an educational pamphlet and those treated with the educational pamphlet alone. Lastly, Alves-Guerreiro et al. (2001) concluded that neither TENS nor action-potential stimulation therapy (APS) nor IF produced a significant hypoanalgesic effect in healthy test subjects. Minder et al. (2003) found IF to have no overall beneficial effect on delayed-onset muscle soreness. In contrast, Jarit et al. (2003) found that home IF therapy may help to reduce pain and swelling in individuals who undergo knee surgery, and Hou et al. (2002) found that IF may have benefit for relieving myofascial pain when used in conjunction with hot packs and range-of-motion exercises.

Only two studies assessing the effectiveness of IF on bone healing were found. Fourie (1997) studied the effectiveness of IF as compared with that of placebo and controls in a randomized, double-blind study of

227 fresh tibial fractures. No significant difference in time-to-healing was noted between groups. Ganne et al. (1996) treated individuals predisposed to nonunion who had suffered mandibular fractures with IF. A retrospective chart review of individuals treated by the same physicians served as the control group. Although three of 10 individuals in the control group had nonunion versus zero of nine in the study group, the study numbers are too small to draw conclusions.

The CTAF evaluated the literature on IF for the treatment of musculoskeletal pain and concluded that this treatment modality has not been shown to be as beneficial as alternative treatments such as NSAIDs and exercise therapy. Although IF was found to be a generally safe technique, it did not meet the CTAF technology assessment criteria for the treatment of musculoskeletal pain.

Current research literature does not support the use of IF for the treatment of pain associated with musculoskeletal disorders or injuries, stimulation of soft tissue healing, or stimulation of bone fracture healing.

MICROCURRENT Electrical Nerve Stimulator (MENS)
MENS is a device that uses small amounts of electrical current (millionths of an amp) to help relieve pain and heal soft tissues of the body. The application of MICROCURRENT to an injured area helps realign the body's electrical current and increase the production of adenosine triphosphate (ATP), resulting in increased healing and recovery, as well as blocking perceived pain. The electrical current is subsensory and usually not felt. MENS differs from TENS in that it uses a significantly reduced electrical stimulation. The goal of TENS is to block pain, while MENS acts on naturally-occurring electrical impulses to decrease pain by stimulating the healing process.

Frequency specific microcurrent (FSM) is a type of microcurrent therapy. The microcurrent device has two separate channels that allow both the frequency and current to be set independently for each channel. According to the Frequency Specific Microcurrent website, specific frequency/current combinations work for specific conditions and only those conditions which include myofascial pain, fibromyalgia, sports injuries, concussion and other health concerns. The majority of research with FSM has been done with the Precision Micro (Precision Microcurrent, Inc, Newberg, OR) microcurrent device.

U.S. Food and Drug Administration (FDA): The FDA has approved many Microcurrent devices and has categorized them as TENS devices intended for pain relief. The device is used to apply an electrical current to electrodes on a patient's skin to treat pain. Precision Micro (Precision Microcurrent, Inc, Newberg, OR) received 510(k) FDA approval in 2004 as a class II device equivalent to predicate TENS devices.

The peer-reviewed literature does not establish the safety and efficacy of MENS or FSM; therefore, no conclusion can be drawn as to its safety or efficacy.

Percutaneous Electrical Nerve Stimulation (PENS)
PENS involves the insertion of a needle below the skin. PENS is similar to TENS except that the needle insertion is adjacent to a nerve. PENS is generally reserved for patients who fail to obtain pain relief from TENS (Hamza, et al., 2000). Very little peer-reviewed scientific literature exists to establish the safety and efficacy of PENS; therefore, no conclusion can be drawn concerning its effect on chronic or postoperative pain.

Percutaneous Neuromodulation Therapy (PNT)
PNT is a variation of PENS which has been developed as a treatment for neck and back pain. This treatment involves insertion of five pairs of needle-like electrodes into the skin of the neck or back. These electrodes stimulate nerve fibers in the deep tissues. A maximum current of 25 milliamps is applied so as not to cause pain or induce muscle contractions. The treatment regimen typically consists of two to three 30-minute sessions per week for two to six weeks.

U.S. Food and Drug Administration (FDA): The Vertis PNT System (Vertis Neuroscience Inc., Seattle, WA) was initially granted marketing approval by the FDA via the 510(k) process on December 21, 2001. The FDA stated that "PNT is indicated for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-

trauma pain" (FDA, 2002). The Vertis PNT Control Unit, with a cervical electrode and cable, received 510(k) approval on September 11, 2002.

Literature Review: Kang et al. (2007) conducted a single-blinded, randomized study of 63 patients with knee pain secondary to osteoarthritis. Twenty-eight patients were randomly assigned to the sham group and 35 to the live treatment group. The study investigated the efficacy of percutaneous neuromodulation pain therapy (PNT) in reducing knee pain and medication consumption during the first week following treatment. Pain levels were rated on a 100-mm visual analog pain scale (VAS). The live group had greater efficacy than the sham group in all time periods; however, only in the immediate post-treatment period did it reach statistical significance (P=.0361). The overall median pain intensity difference over all periods was 14.5 for the live group and 6.5 for the sham group and reached statistical significance (P=.0071). At one week follow-up, the live group reported significantly less medication use (P<.0001) than the sham group. The results of this study are promising, and larger, multicenter studies to better determine treatment efficacy are warranted.

Weiner et al. (2003) conducted an RCT (n=34) to determine the efficacy of PENS, also referred to as PNT, for the treatment of chronic LBP in older adults. Patients were randomized to receive twice-weekly PENS and physical therapy (PT) or sham PENS and PT for six weeks. The primary outcome measures of self-reported pain intensity and pain-related disability were assessed at baseline, six weeks and three months after completion of treatment. Patients randomized to PENS plus PT group displayed significant reductions in pain intensity measures from pre- to post-treatment (p<.001), but the sham PENS plus PT group did not (p=.94). These pain reduction effects were maintained at three-month follow-up. Significant reductions in pain-related disability were also observed at post-treatment (p=.002) for the PENS plus PT group and were maintained at follow-up, while the sham PENS plus PT group did not show reductions in pain-related disability (p=.81). The authors concluded that the results of this preliminary study suggest that PENS may be a promising treatment modality for older adults with chronic LBP. However, larger studies with longer duration of follow-up are needed to validate these findings and support the use of PENS in clinical practice (Weiner, et al., 2003).

A Hayes report on the Vertis PNT system for the treatment of LBP examined four randomized crossover trials (n=34–75) in addition to Weiner et al. (2003). No complications were found to be associated with PNT. Potential complications based on exclusion criteria of studies included heart disease and implanted cardiac pacemaker. According to the Hayes brief, results of these studies suggest that PNT reduces LBP and the disability due to this pain, but the randomized crossover trials provided evidence that the benefits are temporary. In these studies, pain reoccurred between treatment sessions. It was concluded that the current evidence regarding the safety and efficacy of PNT for LBP is promising but insufficient to support its use (Hayes, 2006).

At present, there is insufficient evidence in published peer-reviewed literature to support the efficacy of PENS or PNT as a treatment for pain.

Summary
Electrical stimulation is used in a variety of settings to treat a range of acute and chronic conditions. Despite its widespread use, well-designed, randomized controlled clinical trials to determine the safety and efficacy of the electrical stimulation devices are lacking. There is some peer-reviewed literature to support the use of transcutaneous electrical nerve stimulator (TENS) for the secondary treatment of patients with chronic pain if conventional therapy has failed and, because TENS has been used to treat this condition before evidence-based medicine became available, it is considered as a standard of care by the community.

Literature to support the use of neuromuscular electrical stimulation **(**NMES) for disuse atrophy is limited. However, it is considered standard of care by the medical community in patients with disuse atrophy where the nerve supply to the muscle is intact as a component of a comprehensive rehabilitation program.

There is insufficient evidence to support the safety or efficacy of NMES in the treatment of rheumatoid arthritis; preventing and/or treating post-stroke pain; toning, strengthening and firming of abdominal

muscles; treatment of fecal incontinence; low back pain; Bell's palsy; sensory stimulation for coma patients; motor disorders; cerebral palsy or treatment of chronic ulcers or other conditions.

Conductive garments used in conjunction with TENS or NMES are appropriate when the patient has large areas or numbers of sites to be stimulated or the frequency is such that conventional electrodes, tape, or lead wires are not feasible; the patient is not able to access sites that require stimulation (i.e., back); or the patient has a medical condition (e.g., skin problem) that precludes the use of conventional electrodes, tape, or lead wires.

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
64550	Application of surface (transcutaneous) neurostimulator

HCPCS Codes	Description
E0720	Tens, two lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation device, four or more leads, for multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)

ICD-9-CM Diagnosis Codes	Description
	No specific codes

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
64565	Percutaneous implantation of neurostimulator electrodes; Neuromuscular

HCPCS Codes	Description
E0740	Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer

ICD-9-CM Diagnosis Codes	Description
	All codes

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