



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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## Subject Electrical Stimulators

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### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. 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 benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

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.

### Neuromuscular Electrical Stimulation (NMES)

CIGNA 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.

### Transcutaneous Electrical Nerve Stimulation (TENS)

Some benefit plans have a specific limitation of coverage of transcutaneous electrical nerve stimulation (TENS) units. Please refer to the applicable benefit plan document. If not specifically limited by the benefit plan, CIGNA covers a transcutaneous electrical nerve stimulator (TENS) as medically necessary for EITHER of the following:

- chronic pain, except as noted below, when there is failure of at least a three-month trial of conventional medical management including medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], acetaminophen) and physical therapy
- as an adjunct to conventional post-operative pain management within 30 days of surgery

CIGNA does not cover TENS for ANY other indication, including the following conditions, because each is considered experimental, investigational or unproven:

- acute and chronic headaches
- abdominal pain
- pelvic pain
- temporomandibular joint (TMJ) pain

### Conductive Garment

CIGNA 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.

### Miscellaneous Other Electrical Stimulation Devices

CIGNA does not cover 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)
- cranial electrical stimulation (cranial electrotherapy stimulation)
- electrical sympathetic stimulation therapy
- electro therapeutic point stimulation (ETPS<sup>SM</sup>)
- functional electrical stimulation (FES)
- H-WAVE electrical stimulation

- high-voltage galvanic stimulator (HVG)
- interferential therapy (IFT)
- microcurrent electrical nerve stimulation (MENS), including frequency-specific microcurrent (FSM) stimulation
- pelvic floor electrical stimulation (PFES)
- percutaneous electrical nerve stimulation (PENS)
- percutaneous neuromodulation therapy (PNT)
- peripheral/posterior tibial nerve stimulation (PTNS)
- PrimaBella™ nerve stimulation therapy
- threshold/therapeutic electrical stimulation (TES)

## General Background

Electrical stimulators provide direct, alternating, pulsating and/or pulsed waveform forms of energy. The devices are used to exercise muscles, demonstrate a muscular response to stimulation of a nerve, relieve pain, relieve incontinence, and provide test measurements. Electrodes for such devices may be implanted, indwelling, transcutaneous (needles) or surface. Electrical stimulators may have controls for setting the pulse length, pulse repetition frequency, pulse amplitude, and triggering modes.

### Neuromuscular Electrical Stimulation (NMES)

NMES is the application of electrical current through electrodes on the skin to targeted muscles to elicit muscle contraction and relaxation. NMES is proposed to promote muscle restoration and to prevent or diminish muscle atrophy and spasms and is an established treatment modality for disuse atrophy when the nerve supply to the muscle is intact. NMES is typically used as a component of a comprehensive rehabilitation program. Protocols in the literature recommend no more than two hours of NMES treatment within a 24-hour period and the treatment plan is typically re-evaluated every 30 days. Compared to TENS, NMES delivers a stronger current with a wider pulse width, and TENS is primarily indicated for the management of chronic pain.

**U.S. Food and Drug Administration (FDA):** Neuromuscular electrical stimulators are 510(k) FDA approved as Class II devices. An example of a NMES device is the EMS 7500 (Koalaty Products, Ind., Roswell, GA). The device is approved for “(1) relaxing muscle spasms, (2) increasing local blood circulation, (3) immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) muscle re-education, (5) maintaining or increasing range of motion, and (6) preventing or retarding disuse atrophy.”

**Literature Review - Disuse Atrophy:** Systematic reviews and randomized controlled trials support NMES for the treatment of disuse atrophy and reported that NMES was as effective as, or more effective than, exercise (Bax, 2005; Lieber, et al., 1996). NMES is a well-established treatment modality for disuse atrophy in patients where the nerve supply to the muscle is intact.

**Literature Review – Other Indications:** There is insufficient evidence to support the effectiveness of NMES in the prevention and/or management of multiple conditions including: cancer; congestive heart failure; chronic obstructive pulmonary disease (COPD); deep vein thrombosis; dysphagia; knee rehabilitation following injury or surgical intervention; muscular dystrophy; muscle wasting and weakness associated with cancers; cerebral palsy; stroke; toning, strengthening and firming of abdominal muscles; rheumatoid arthritis; fecal incontinence; low back pain; Bell’s palsy; sensory stimulation for coma patients; motor disorders; and chronic ulcers.

**Heart Failure:** Arena et al. (2010) conducted a systematic review of the literature to evaluate the evidence supporting NMES and inspiratory muscle training (IMT) for the treatment of systolic heart failure. Thirteen NMES studies met inclusion criteria, ten were randomized controlled trials. Although the studies reported improvement in aerobic capacity, peak oxygen uptake and strength and endurance of muscle groups, the studies were limited by patient population (i.e., mostly males), diverse NMES training protocols, variation in the type of muscle contraction elicited (i.e., titanic vs. twitch), the use of different muscle groups and different comparators. The percent improvement in peak oxygen uptake was consistently greater with conventional therapy (i.e., bicycle/treadmill).

Sillen et al. (2009) conducted a systematic review of randomized controlled trials to analyze the role of NMES in strength, exercise capacity, and disease-specific health status in patients with congestive heart failure (n=9 studies) and chronic obstructive pulmonary disease (n=5 studies) with disabling dyspnea, fatigue, and exercise intolerance. The limited number of studies, heterogeneous patient populations and variability in NMES methodology prohibited the use of meta-analysis. Although some of the studies reported significant improvements with NMES compared to no exercise or usual care, outcomes, including adverse events, were conflicting. Additional studies are indicated to provide sufficient evidence to establish the clinical utility of NMES in this patient population.

**Knee Surgery:** Kim et al. (2010) conducted a systematic review of randomized controlled trials (n=8) to assess the effectiveness of NMES on “quadriceps strength, functional performance, and self-reported function after anterior cruciate ligament reconstruction.” Control interventions included: therapeutic exercises, EMG biofeedback, TENS plus exercises, and weight-bearing exercises. Quadriceps strength outcomes varied with some studies favoring NMES while others reported equivocal results or favored control interventions. One study each reported functional testing (n=20) and patient self-reported outcomes (n=43). Although some studies reported improvement following NMES, this analysis was limited by the use of various NMES regimens (e.g., treatment duration ranged from three to 11 weeks, number of sessions ranged from 12–105) and overall, only one follow-up visit occurred immediately following completion of treatment sessions. There is insufficient evidence to support clinical meaningful benefit of NMES on functional performance.

In a systematic review of randomized controlled trials, Monaghan et al. (2010) assessed the effectiveness of NMES in strengthening quadriceps before and after total knee replacement. Two studies met inclusion criteria. NMES plus exercise resulted in better quadriceps muscle activation compared to exercise alone (n=39), but was not maintained at the 12-week follow-up. No significant differences were reported in either study for maximum voluntary isometric torque or endurance between the NMES group and the control group.

In a 2008 systematic review of anterior cruciate ligament reconstruction (ACL) rehabilitation, Wright et al. reported that 14 randomized controlled trials had evaluated postoperative NMES following ACL reconstruction. Because of the variety of parameters in the studies; poor study quality; heterogeneous patient populations; and the lack of randomization, blinding and independent observers, the authors noted that it was difficult to make generalized conclusions regarding NMES, and it did not appear to be a requirement for successful ACL reconstruction rehabilitation.

**Stroke:** In a randomized controlled trial (n=60), Hsu et al. (2010) compared high-NMES and low-NMES to a control group (standard rehabilitation) for the treatment of upper-extremity function in acute stroke patients. The low NMES group received 30 minutes of stimulation per day and the high-NMES group received 60 minutes per day, five times per week, for four weeks. All patients received standard rehabilitation. Compared to the control group, the NMES groups showed significant improvement in the Fugl-Meyer Motor Assessment (p=0.003) and Action Research Arm Test scales (p=0.016) at week four and week 12. There were no significant differences between low- and high-NMES stimulation. No significant differences between the groups were reported on the motor activity log. Limitations of the study include the small patient population, short-term follow-up, and 12 patients lost to follow-up.

**Professional Societies/Organizations:** The American Society of Anesthesiologists Task Force on Chronic Pain and the American Society of Regional Anesthesia and Pain Medicine practice guidelines (2011) stated that NMES may be used as part of a multimodal treatment of patients with painful peripheral nerve injuries unresponsive to other therapies.

In the evaluation of the literature regarding electrical stimulation for the treatment of spasticity in multiple sclerosis, the Multiple Sclerosis Council for Clinical Practice Guidelines (2005) stated that “surface electrical stimulation may be of benefit in reducing spasticity in persons with MS, but there is currently no evidence to support this supposition at this time.”

### **Transcutaneous Electrical Nerve Stimulation (TENS)**

Generally, persistent ongoing pain for three to six months or longer is considered chronic pain, though a clear and consistent definition of when pain becomes chronic has not been established. Consideration as to the underlying illness, pathophysiology and natural course of the condition may be factors in determining when an acute pain condition becomes chronic or when a chronic illness develops a component of chronic pain due to

the underlying disorder. For instance, chronic pain has also been described as pain that continues a month or more beyond the usual recovery period for an injury or illness or that goes on for months or years due to a chronic underlying medical or orthopedic condition. Chronic pain suggests a course of illness that will require ongoing assessment and management and is not expected to remit in a foreseeable interval of time. The pain may be excruciating, constant and interfere with daily activities. Pain that is chronic, persistent and not relieved by conventional medical or surgical management is considered intractable. There may have been an initial condition or mishap (e.g., infection, injury, sprained back) that became chronic or an ongoing condition (e.g., arthritis, cancer). Other people suffer chronic pain in the absence of any past injury or evidence of body damage and the etiology is unknown. Common chronic pain complaints include joint pain, low back pain, cancer pain, arthritis pain, neurogenic pain (i.e., pain resulting from damage to the peripheral nerves or to the central nervous system itself) and/or psychogenic pain (pain not due to past disease or injury or any visible sign of damage inside or outside the nervous system). The treatment of chronic pain is typically multidimensional and may include pharmacotherapy, exercise, relaxation, acupuncture and/or behavior modification. Depending on the condition, transcutaneous electrical stimulation (TENS) or surgical intervention may be appropriate (American Association for Chronic Pain, 2011; National Institute of Neurological Disorders and Stroke, 2011; Singh, et al., 2011).

A TENS device consists of an electronic stimulus generator that transmits pulses of various configurations through electrodes on the skin to stimulate the peripheral nerves for the purpose of pain management. Conventional TENS or high frequency TENS delivers 40–150 hertz (Hz) compared to acupuncture-like TENS that delivers a low frequency at 1–10 Hz. Pulsed TENS uses low-intensity firing in high-frequency bursts at 100 HZ. TENS has been used for a number of applications, including acute and chronic pain, postoperative pain, obstetrical pain, and pain associated with medical procedures.

**U.S. Food and Drug Administration (FDA):** TENS are approved by the FDA 510(k) process as a Class II device for the relief and management of chronic intractable pain. Examples of these devices include the Empi Active Transcutaneous Nerve Stimulator (Empi, Inc., Clear Lake, SD), the StimPad™ TENS System (AEMED, Inc. West Palm Beach, FLA), Calmare® Pain Therapy Treatment (Competitive Technology, North Attleboro, MA).

**Literature Review - Acute Postoperative Pain and Chronic Pain:** The evidence in the peer-reviewed literature supports TENS for the treatment of pain in the acute post-operative period (i.e., within 30 days of surgery) and as a secondary treatment option for patients with chronic pain when conventional therapies (e.g., nonsteroidal anti-inflammatory drugs, physical therapy) have failed. TENS is a well-established treatment modality for these indications. Systematic reviews, meta-analysis and randomized controlled trials reported a reduction in pain and analgesic use in the treatment of acute post-operative pain and chronic pain (e.g., back pain, osteoarthritis of the knees) following TENS (Freyne and Falcoz, 2010; Jin, et al., 2010; Pieber, et al., 2010; Emmiler, et al., 2008; Cipriano, et al., 2008; Bjordal, et al., 2007; Solak, et al., 2007; Bjordal, et al., 2003).

**Literature Review - Other Indications:** The evidence in the published peer-reviewed scientific literature has not established the effectiveness of TENS for the treatment of any other indications including, but not limited to: acute pain, acute and chronic headaches; abdominal pain, asthma, chemotherapy-induced pain, chronic leg ulcers, colonoscopy, drug withdrawal (e.g., opiate addiction), dysmenorrhea, fracture healing, hypertension, mandibular disorders (e.g., neuromuscular orthodontics; temporomandibular joint [TMJ]), motion sickness, nausea and vomiting of pregnancy, overactive bladder, pain associated with childbirth (i.e., labor), pelvic pain, post-traumatic acute pain, rotator cuff tendinitis, stroke rehabilitation, suspected placental insufficiency, tinnitus, urinary incontinence, vestibulodynia, and unstable angina. Overall, systematic reviews, randomized controlled trials and case series have reported that there was no improvement with TENS for these indications or that conclusions could not be made due to the poor methodology of the studies. Study limitations included small heterogeneous patient populations with short-term follow-ups, data insufficient or conflicting data, and the application of TENS varied (e.g., physician applied vs. patient applied, location of electrodes). Evidence supporting TENS for these indications is lacking nor is TENS an established treatment modality. The clinical utility of TENS has not been established for all other indications.

**Acute Pain:** Walsh et al. (2009) assessed the analgesic effectiveness of TENS in acute pain for adults (n=919) in a systematic review of 12 randomized controlled trials. The types of acute pain included procedural pain (e.g. cervical laser treatment, venipuncture, screening flexible sigmoidoscopy) and nonprocedural pain (e.g.

postpartum uterine contractions, rib fractures). The authors were unable to make any definitive conclusions due to the insufficient extractable data.

**Back Pain:** Khadiilkar et al. (2008) conducted a systematic review to determine if TENS was more effective than placebo for the management of chronic low back pain. Four “high-quality” randomized controlled trials (n=585) met inclusion criteria. Due to conflicting evidence, the authors were unable to determine if TENS was beneficial in reducing back pain intensity. Two trials involving 410 patients reported that TENS did not improve back-specific functional status, the level of disability from the pain, the use of medical services or work status. There were no significant differences in outcomes when conventional TENS was compared to acupuncture-like TENS.

**Cancer Pain:** Robb et al. (2009) conducted a systematic review of the literature to evaluate TENS for the treatment of cancer-related pain. Two randomized controlled trials (n=64) met inclusion criteria. Meta-analysis was not conducted due to the disparities between patient population, mode of TENS, treatment duration, and outcome measures prevented meta-analysis. There is insufficient evidence to support TENS for the treatment of cancer-related pain.

**Colonoscopy:** Amer-Cuenca et al. (2011) conducted a randomized controlled trial (n=90) to evaluate the effectiveness of TENS in controlling pain in unsedated patients undergoing screening colonoscopy. Patients were randomized to one of three groups: control group (n=30), active TENS (n=30), or placebo TENS (n=30). The control group received hospital standard protocol for unsedated colonoscopies without any kind of sedation or analgesia. Pain was assessed five minutes into the procedure and at the end of the procedure using a visual analogue scale (VAS) and a five-point Likert scale. The TENS group reported a  $\geq 50\%$  reduction in the VAS scores compared to the placebo and control group ( $p < 0.001$ ). There was also a significant reduction on the Likert scale scores in the TENS group compared to the placebo and control groups ( $p = 0.009$ ). There were no significant differences between the groups in bloating sensation during the procedure and the duration of the procedure. Greater than 50% pain relief was achieved by 17 TENS patients, three placebo patients and six control patients ( $p < 0.001$ ). Author-noted limitations of the study included: the active TENS group’s experience of pain might have been affected by the potential distraction of continuously adapting stimulus intensity and the use of VAS as a measurement of pain. Another limitation is the small patient population.

**Dementia:** Cameron et al. (2003; updated 2005) conducted a systematic review on TENS for the treatment of dementia. Nine randomized controlled trials met inclusion criteria, and three were included in meta-analysis. A statistically significant improvement was reported immediately following therapy in: delayed recall of 8 words and motivation in one trial, each and face recognition in two trials and motivation in one trial. The authors concluded that there was insufficient data for definitive conclusions to be drawn.

**Dysmenorrhea:** In a systematic review of seven randomized controlled trials (n=164), Proctor et al. (2009) evaluated the effectiveness of low-frequency TENS (acupuncture-like TENS, 1–4 hertz [Hz]) and high-frequency TENS (conventional TENS, 50–120 Hz) (n=5) for the treatment of primary dysmenorrhea. Studies compared TENS to placebo, no treatment or medical treatment. Overall, high-frequency TENS was reported more effective than placebo TENS for relief of pain. There was no difference in pain relief with low-frequency TENS compared to placebo. There were conflicting results regarding whether high-frequency TENS was more effective than low-frequency TENS. Due to the small patient populations, various methods of the application of TENS, and the lack of precision in the comparisons, clear recommendations for clinical applications could not be made.

**Labor:** In a non-randomized prospective comparative trial (Peng, et al., 2010), pain relief during labor was evaluated in 160 nulliparous women who were treated with acu-TENS and compared to a control group of 145 women who did not receive acu-TENS. Four specific acupuncture points were used: Hegu (LI4), Neiguan (PC6), Danshu (BL19) and Weishu (BL21). The visual analogue scale (VAS) was used to assess the pain every hour until delivery. In the treatment group, 68.6% of women experienced a  $> 25\%$  reduction in pain (primary outcome). The latent phase in the TENS group was significantly longer than in the control group ( $p < 0.05$ ). The TENS group experienced significantly less postpartum hemorrhage than the control group ( $p < 0.05$ ). There was no significant difference between the groups in delivery mode and neonatal outcomes. Limitations of the study include the small patient population and the lack of randomization.

Dowswell et al. (2009) conducted a systematic review on the use of TENS during labor. A total of 19 randomized controlled trials (n=1671) comparing TENS to pharmacotherapy or placebo met inclusion criteria.

TENS was applied to the back (n=15), acupuncture points (n=2), and cranium (n=2). Overall, there were no significant differences between pain ratings in the TENS group and the control groups. In cases where TENS was used as an adjunct to epidural analgesia, there was no evidence that it reduced pain. There was no consistent evidence that TENS had any impact on interventions and outcomes of labor.

**Neck Pain:** Following a systematic review of the literature regarding electrotherapy, including TENS, for neck pain, Kroeling et al. (2009) concluded that no definitive statements could be made regarding the efficacy and clinical usefulness of these modalities. Eleven TENS trials (n=7-30) met inclusion criteria including: TENS compared to placebo or another modality (i.e., ultrasound, manual therapy, electrical muscle stimulation); TENS plus another therapy (i.e., hot packs, infrared, exercises, neck collar and/or analgesic) compared to the other therapy alone; or different TENS regimens. The authors concluded that “very low quality” evidence showed that TENS might relieve pain better than placebo or electrical muscle stimulation but not as well as exercise and infrared and possibly as well as manual therapy and ultrasound.

**Osteoarthritis of the Knee:** Rutjes et al. (2009) conducted a systematic review of the literature to evaluate transcutaneous electrical nerve stimulation for the treatment of osteoarthritis of the knee. Thirteen randomized and quasi-randomized trials (n=465) using TENS met inclusion criteria. Due to the heterogeneity of the studies and poor methodology, the authors could not confirm the effectiveness of TENS for this condition.

**Phantom Pain and Stump Pain:** Mulvey et al. (2010) conducted a systematic review of randomized controlled trials to assess the effectiveness of TENS for the treatment of phantom pain and stump pain following amputation in adults. No studies were identified.

**Rheumatoid Arthritis:** In a systematic review of the literature, Brosseau et al. (2003) evaluated the effectiveness of TENS for the treatment of rheumatoid arthritis of the hand. Three randomized controlled trials (n=78) met inclusion criteria. Conventional TENS (c-TENS) and acupuncture-TENS (acu-TENS) were compared to either placebo or each other. Results were conflicting on the effect of TENS on pain outcomes. Acu-TENS was beneficial for reducing pain intensity and improving muscle power scores compared to placebo. No clinical benefit on pain was reported with C-TENS compared to placebo. C-TENS resulted in a clinical benefit on the patients' assessment of change compared to acu-TENS. The authors concluded that more well designed studies with a standardized protocol and adequate number of subjects were needed to fully identify the effect of TENS for the treatment of RA of the hand.

**Stroke:** NG and Hui-Chan (2009) conducted a randomized controlled trial (n=109) to determine if TENS would improve functional walking performance (i.e., gait velocity, walking endurance and functional mobility) in hemiparetic stroke patients with spastic plantar flexors. In addition to a control group (n=29), patients were assigned to one of three intervention groups: TENS only (n=28), TENS plus exercise (n=27) or placebo stimulation plus exercise (n=25). Each patient self-administered 20 sessions, five days per week for four weeks. Each group received 60 minutes of TENS and the exercise groups received an additional 60 minutes of exercise following TENS or placebo stimulation. Final follow-up occurred four weeks after the treatment ended. At the final follow-up compared to all other groups, significant improvements were seen in the TENS plus exercise group in gait velocity (p<0.001) and reduction in timed up and go scores (P<0.01). The TENS plus exercise group covered significantly more distance in the 6-minute walk test (6MWT) (p<0.01) compared to the control group and the TENS only group. Additional studies with larger patient populations and long-term follow-up are indicated to validate the results of this study. The generalizability of this study is limited to stroke patients with moderate to severe spasticity in the ankle plantar flexors. The frequency, duration, and intensity of combined rehabilitation programs have not been established.

Yan et al. (2009) conducted a randomized controlled trial (n=62) to investigate whether TENS, when applied to acupuncture points in patients after acute stroke, decreased spasticity and/or increased muscle strength and was more effective than placebo stimulation and standard rehabilitation. Patients were randomized to TENS, placebo-TENS, or standard rehabilitation. Stimulation was applied to four acupuncture points in the affected lower leg for 60 minutes, five days a week for three weeks. Compared to placebo or rehabilitation, TENS significantly increased the number of patients with normal tone and ankle dorsiflexor strength and decreased the co-contraction ratio (p<0.05). Overall, the TENS patient walked two to four days earlier than the other patients, but the difference was not significant between the three groups.

**Urinary Incontinence:** In a randomized controlled trial, Hagstroem et al. (2009) evaluated the effectiveness of sacral TENS in 27 children, ages 5–14 years, with severe nonneuropathic daytime urge incontinence (i.e., median of 7 wet days per week) refractory to standard urotherapy and anticholinergics. Anticholinergics were discontinued two weeks prior to the onset of the study and detrusor overactivity was confirmed by testing. Patients were randomized to TENS (FemiScan™ Stim, Mega Electronics, Ltd., East Longmeadow, MA) or to sham therapy. TENS was applied two hours per day for four weeks. Five children had no response to TENS and eight children had a partial response. Two children in the sham group improved significantly. With the exception of the number of wet days per week ( $p < 0.05$ ), there were no significant differences in pre- and post-treatment parameters (e.g., incontinence scores, number of incontinence episodes, voiding frequency) in the two groups. The change in scores in wet days per week and incontinence episodes per day were significantly greater in the TENS group vs. the sham group ( $p < 0.05$  and  $p < 0.01$ , respectively). The TENS group had a significant decrease in incontinence scores, wet days per week, number of daily urge incontinence and improved response to urgency ( $p < 0.01$  each) compared to no significant changes in the sham group. Bladder reservoir function did not change in either group. Limitations of the study include the small patient population and short-term follow-up.

**Vestibulodynia:** Murina et al. (2008) assessed the efficacy of TENS in the treatment of 40 women with vestibulodynia. The women were randomized to either TENS or sham and received treatment twice a week for 20 sessions. At the three month follow-up, visual analogue scale scores and short-form McGill-Melzack Pain Questionnaire scores improved significantly ( $p = 0.004$ ,  $p = 0.001$ , respectively) in the TENS group compared to the sham group. Three of 15 women in the TENS group relapsed three months following the end of the study. No adverse events were reported. Limitations of the study include the small patient population and short-term follow-up.

**Professional Societies/Organizations:** Following a systematic review of none-pharmacological treatment modalities for dementia, the Department of Veterans Affairs Health Services Research and Development Services (VA/DOD) (2011) stated that three randomized controlled trials found no significant effects on sleep disturbance or behavioral symptoms following treatment and six-weeks thereafter. Possible benefits of TENS for the treatment of dementia could not be made.

The VA/DOD (2010) practice guideline on the management of stroke rehabilitations stated that there was insufficient evidence to support the use of TENS and its mechanism of action for stroke rehabilitation is unknown. However, the guideline stated that TENS could be considered as an adjunctive treatment for enhancing recovery of gait function in this patient population.

In practice guidelines for chronic pain management, the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine (2011) recommended TENS as part of a multimodal approach to pain management for the treatment of patients with chronic pain (e.g., back pain, neck pain, phantom limb pain).

In a 2010 technology assessment on the efficacy of TENS in the treatment of pain in neurologic disorders, the American Academy of Neurology (Dubinsky et al., 2010) stated that based on the available evidence, TENS is not recommended for the treatment of low-back pain, but is recommended for the treatment of painful diabetic neuropathy.

In their chronic pain medical treatment guidelines, the Work Loss Data Institute (2009) recommended TENS as a treatment option for acute post-operative pain in the first 30 days following surgery. They also recommended TENS as a secondary treatment modality on a one-month trial bases for chronic intractable pain of at least three months' duration for conditions such as neuropathic pain (e.g., diabetic neuropathy, post-herpetic neuralgia), multiple sclerosis, phantom limb pain, complex regional pain syndrome or spasticity). They noted that there is a lack of evidence supporting the efficacy of TENS for chronic pain and stated that TENS should be used as an adjunct to an "evidence-based restorative program."

Following a systematic review of randomized controlled trials of 17 nonpharmacologic therapies for low back pain, the American Pain Society and the American College of Physicians (2007) stated that TENS had not been shown to be effective for acute, subacute or chronic low back pain (Chou and Huffman, 2007).

In their US Headache Consortium guidelines for the treatment of migraine headaches, the American Headache Society (2006) stated that the empirical data regarding the treatment of migraines with TENS was limited and evidence-based recommendations could not be made. Only two studies met inclusion criteria.

### **Conductive Garments**

Conductive garments are fabric electrodes placed between an electrical stimulator and a patient's skin for the delivery of electrical stimulation. They are an established alternative to standard electrode to aid in the treatment of 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. The electrodes may also be indicated when sites requiring stimulation are not accessible by the patient with conventional electrodes, tapes or lead wires (i.e., back) and/or when medical conditions (e.g., skin problems) preclude the use of conventional electrodes, tapes or lead wires.

**U.S. Food and Drug Administration (FDA):** AG Garments (San Diego, CA) conductive electrodes are Class II, 510(k) approved by the FDA "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 electromedicine, 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).

**U.S. Food and Drug Administration (FDA):** An example of a device used for bioelectric therapy is the Matrix PRO ElecDT (Matrix Electromedical, Inc., Las Vegas, NV) which was 510(k) approved by the FDA as an interferential current therapy device.

**Literature Review:** There is insufficient evidence in the published peer-reviewed scientific studies to support the safety and effectiveness of bioelectric therapy. Well-designed, randomized controlled clinical studies are needed to determine the clinical utility of electroceutical therapy in the treatment of patients with acute or chronic pain.

### **Cranial Electrical Stimulation**

Cranial electrical stimulation (CES), also called electrotherapy, electrotherapeutic sleep, electrosleep, electric cerebral stimulation, cranial transcutaneous electrical nerve stimulation, cerebral electrotherapy, transcranial electrotherapy, transcranial electrical stimulation, transcranial direct electrical stimulation (tDCS), transcerebral electrotherapy, neuroelectric therapy, and craniofacial electrostimulation, delivers low level electrical stimulation (i.e., microcurrent) to the brain through electrodes that are attached to the ear lobes or behind the ears. It has been proposed that CES's direct effect on the brain's limbic system, hypothalamus, reticular activation system, and/or the autonomic nervous system can control the symptoms of various conditions. This therapy is not to be confused with transcranial magnetic stimulation or vagus nerve stimulation. CES has been proposed for the treatment of anxiety, depression, insomnia, substance abuse, fibromyalgia, Alzheimer's, attention-deficit/hyperactivity disorder (ADHD), asthma, spastic colitis, tension headaches, hypertension, chemotherapy symptoms in cancer patients, burn patients, and other pain-related disorders.

**U.S. Food and Drug Administration (FDA):** CES devices are approved under the FDA 510(k) class III process for the treatment of insomnia, depression, or anxiety. Examples of these devices include the Cranial Electrical Nerve Stimulator (Johari Digital Healthcare Ltd., Fall CITY, WA), Alpha-Stim<sup>®</sup> (Electromedical Products, Inc., Hawthorne, CA), and LISS Cranial Stimulator and Fisher-Wallace Cranial Stimulator by Medical Consultants Intl. Ltd. (Glen Rock, NJ). Some devices are approved for use by the patient at home.

**Literature Review:** The evidence in the published peer-reviewed literature does not support the effectiveness of CES for any indication. Studies consist of randomized trials with small patient populations, short-term follow-ups, and conflicting outcomes.

**Alzheimers:** Rose et al. (2009) conducted a randomized controlled trial to compare the short-term effects of CES (Alpha-Stim) (n=19) to sham stimulation (n=19) on sleep disturbance, depressive symptoms, and subjective appraisal in individuals who were the primary caregivers for spouses with Alzheimer's disease. Subjects used CES 60 minutes per day for four weeks and completed a daily log. At the end of four weeks, there were no significant differences in overall sleep disturbances, sleep quality, or sleep onset latency scores. The CES group did report a nine-minute decrease in sleep onset latency compared to a one minute increase in the sham group. There were no significant differences between the groups in depressive symptoms or in burden, mastery, impact or satisfaction of the care giving situation.

**Fibromyalgia:** Lichtbroun et al. (2001) compared the outcomes of fibromyalgia patients randomly assigned to CES (Alpha-Stim) (n=20), sham (n=20), or a control group (n=20). Self-treatments were administered for 60 minutes per day for three weeks. CES treatments resulted in a significant improvement in tender point scores (p<0.001), and self-rated pain scores (p<0.02), quality of sleep (p<0.02), quality of life p<0.03), and feelings of well-being (p<0.05). Similar significant gains were reported in the sham and control patients who switched to CES at the end of the initial three weeks. No significant gains were reported by the sham or control groups.

**Spinal Cord Injury:** In a randomized controlled trial, Tan et al. (2006) evaluated CES (Alpha-Stem) (n=18) and sham stimulation (n=20) for the treatment of chronic pain in men with spinal cord injury. Patients administered their treatment at home for 21 consecutive days for 60 minutes per day and kept a log of their pain immediately before and after treatment. At the end of the 21 days, patients were interviewed in the clinic and the sham participants were allowed to use active CES for an additional 21 days. There were no significant differences between the groups in pain ratings following treatment, but the average change in daily pain intensity and interference prior to and following treatment were significantly better for the CES group and the sham group (p=0.03, p=0.004, respectively). A significant reduction in post-treatment pain was reported by the sham group subjects who switched to CES (n=17) (p=0.003). The authors noted that a limitation of the study was the inability to generalize the outcomes to a female population, and the lack of evaluation of CES on psychological distress, quality of life, and analgesic consumption.

### **Electrical Sympathetic Stimulation Therapy**

Electrical sympathetic stimulation therapy is a form of electrical stimulation of the peripheral nerves by applying eight electrodes bilaterally to the lower legs, feet, arms and hands. The therapy is proposed for the treatment of chronic, intractable pain. Bilateral application of the electrodes is proposed to target the autonomic nervous system, and create a systemic effect of pain relief. Treatments are typically one hour in duration and may be administered in a physician's office or at home.

**U.S. Food and Drug Administration (FDA):** Sympathetic therapy devices are approved by the FDA 510(k) process. Two such devices are the Dynatron STS and the Dynatron STS RX, a home device (Dynatronics Corp., Salt Lake city, UT). The devices are indicated for "symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain" (FDA, 2001).

**Literature Review:** The evidence in the published peer-reviewed scientific literature does not support the safety and effectiveness of sympathetic therapy. Studies are primarily in the form of case series with small patient populations and short-term follow-ups (Guido, 2002).

### **Electro Therapeutic Point Stimulation (ETPS<sup>SM</sup>)**

ETPS neuromechanical therapy or neuropathic acupuncture involves the detection and treatment of chronic intractable neuromyofascial pain using the TENS US Unit (Acumed Medical Supplies, LTD, Stanford, CT). The transcutaneous device detects treatment points on the skin and applies brief, concentrated electrical microstimulation in short bursts. Traditional TENS units apply alternating current compared to the direct current applied by ETPS. Depending on how the device is programmed, the therapy is also proposed to decrease circulation and assist in resolution of swelling and pain or to increase circulation to enhance immune response and neural regeneration. The treatments can be self-administered by the patient at home (Acumed 2010; Hocking, 2002).

**U.S. Food and Drug Administration (FDA):** The TENS US Unit is approved by the FDA 510(k) Class II device as the TENS Pro 900 for the treatment of chronic intractable pain.

**Literature Review:** There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and effectiveness of ETPS. The available studies are primarily in the form of case reports and case series with small patient population and short-term follow-ups.

### **Functional Electrical Stimulation (FES)**

FES or functional neuromuscular stimulation (FNS) attempts to replace stimuli from destroyed nerve pathways to assist neurologically impaired patients (e.g., spinal cord injury, stroke) with functional movement and to suppress spasticity. FES is a high-intensity (25–100 milliamps), short duration therapy that may be delivered for 20 minutes to one hour, several times a week, for months. For the device to be effective, the peripheral nerve must be intact.

FES is proposed for multiple indications, including:

- to assist ambulation in paraplegics (e.g., Parastep<sup>®</sup> I System, Sigmedics, Inc., Fairborn, OH). Parastep is a microcomputer controlled walker proposed to aid standing, walking, balance and stability in individuals with a spinal cord injury for whom gait training and standing are indicated. Using surface electrodes, the device delivers electrical current to peripheral nerves in the lower extremities. Parastep is a proposed alternative to traditional orthotics and bracing;
- as a means of stationary exercise to prevent or reduce muscle atrophy in upper and lower extremities (e.g., ERGYS 2; Therapeutic Alliance, Inc., Fairborn, OH). The ERGYS 2 provides cycling activity proposed to improve muscle strength and circulation in the lower extremities;
- to improve ambulation in patients with gait disorders such as drop foot, hemiplegia due to stroke, cerebral injury, or incomplete spinal cord injury (e.g., Walkaide<sup>™</sup> stimulator; Neuromotion, Edmonton, Alberta, Canada; NESS L300 foot drop system, Bioness Inc., Valencia, CA). WalkAide is a device that attaches to the leg just below the knee and is proposed to counteract foot drop and improve mobility during walking by stimulating the peroneal nerve. The Ness L300 is a similar device that also attaches below the knee, provides nerve stimulation and is proposed to assist the individual with foot drop to walk with increased balance and speed.
- to provide range of motion and function in patients with upper limb paralysis or hemiplegia (NESS H200 hand rehabilitation system [previously known as the Handmaster], Bioness Inc., Valencia, CA). NESS H200 is for use by an individual with hand paralysis. The device attaches to the lower forearm and is proposed to activate various muscle groups, enhancing grip and allowing opening and closing of the hand.

**U.S. Food and Drug Administration (FDA):** FES devices, such as the Parastep, that have been proposed for restoring ambulation to paraplegics are regulated by the FDA's premarket approval (PMA) process.

Functional electrical stimulators that are used to provide stationary exercise for paraplegics, to correct gait disorders, or to provide range of motion and function are approved by the FDA 510(k) process as Class II devices. The RT300 FES cycle ergometer (Restorative Therapies, Inc., Baltimore, MD) is approved as a powered muscle stimulator for "general rehabilitation for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation and maintaining or increasing range of motion" (FDA, 2009). Other Restorative FES devices include the RT300 Leg, RT300 Leg and Arm, RT300 Arm, RT300 for children.

### **Literature review**

**Assist Ambulation in Paraplegics:** Studies investigating FES (i.e., Parastep) were published in 2000 or before and are primarily case series with small patient populations and short-term follow-ups. Brissot et al. (2000) investigated the motor performances of Parastep in 15 thoracic-spine injured patients (T3-T11). Patients had to have a stable neurologic and orthopedic status and be at least six months status-post injury and/or restorative surgery. Two patients did not complete the required training. Follow-up occurred at  $40 \pm 11$  months. After a mean 20 sessions, the patients achieved independent ambulation with a mean walking distance of  $52.8 \pm 69$  meters (m), and a mean speed of  $0.156 \pm 0.14$  m/second. At the final follow-up five patients were using the Parastep regularly and all patients used it for physical fitness and not for functional ambulation. According to the

authors the high ratio of energy cost of the use of the device may have explained its limited use in daily activity. The authors also noted that “the Parastep approach has very limited applications for mobility in daily life, because of its modest performance associated with high metabolic cost and cardiovascular strain. However, it can be proposed as a resource to keep physical and psychological fitness in patients with spinal cord injury.”

Graupe and Kohn (1998) reported on approximately 400 paraplegic patients with T4-T10 spinal cord injuries that had used Parastep and successfully achieved standing and at least 30 feet of ambulation using the device.

Gallien et al. (1995) reported on 12 of 13 spinal cord injury (T4-T10) paraplegics who progressed to independent ambulation with the use of Parastep. Only three patients completed the 32 required training sessions. The average walking distance was 76 m, with a maximum of 350 m, and the mean speed  $0.2 \text{ m} \cdot \text{s}^{-1}$ . At 15 months follow-up, four patients used their device regularly as an orthosis for walking, and all patients used it as an active means for exercise and not to increase ambulation autonomy.

**Stationary Exercise to Prevent or Reduce Muscle Atrophy in Upper and Lower Extremities:** Randomized controlled trials using various FES devices have evaluated FES cycling (MOTOmed<sup>®</sup>, RECK GmbH, Betzenweiler, Germany) compared to passive cycling (n=35) (Ambrosini, et al., 2011); FES (H200 device) combined with self-directed exercise vs. exercise alone (n=23) (Weber, et al., 2010); FES cycling (device not given) with standard rehabilitation vs. rehabilitation alone (n=20) (Ferrante, et al., 2008); and with arm and hand rehabilitation comparing FES (Compex Motion, Compex SA, Switzerland) to conventional therapy (n=23) (Mangold, et al., 2009). Some studies reported no significant differences with FES. Due to the small patient populations, short-term follow-ups (e.g., 4–12 weeks) and conflicting results, the effectiveness of FES for the treatment of stroke patients has not been established.

**Improve Ambulation in Patients with Gait Disorders:** FES has been proposed for improving ambulation in patients with gait disorders such as drop foot, hemiplegia due to stroke, cerebral injury, or incomplete spinal cord injury: In a randomized controlled trial (n=74), Field-Fote and Roach (2011) evaluated whether there was a difference in walking speed and distance using four locomotor training regimens for patients with chronic spinal cord injuries. The regimens included treadmill-based training with manual assistance (TM) (n=19), treadmill-based training with bilateral electrical stimulation (TS) (Digitimer DS7AH, Digitimer Ltd, Welwyn Garden City, Herts, UK) (n=22), overground training with electrical stimulation (OG) (n=18) (WalkAide<sup>™</sup>), and treadmill-based training with locomotor robot (LR) (Lokomat Robotic Gait Orthosis, Zurich, Switzerland) (n=15). Training was administered five days per week for 12 weeks. There was a statistically significant improvement in walking speed ( $p < 0.001$ ) in the TM, TS and OG groups and overall time effect on training ( $p < 0.0001$ ). There was a significant improvement in walking distance in the TS and OG groups. Distance gain was greater for OG. Post hoc testing indicated the increase in “time X group” interaction in the OG group was significantly greater than the other groups ( $p \leq 0.01$ ). Effect sizes for speed ( $d = 0.43$ ) and distance ( $d = 0.28$ ) were largest with OG. Effect sizes for speed were the same for TM and TS ( $d = 0.28$ ). There was no effect from LR. The Lower Extremity Motor Scores increased 8%–13%, with no significant between group differences. Ten patients were available for an average 20.3 month follow-up (4 OG and 6 in the other groups). These subjects had declined an average of 0.06 meter per second (m/s) in walking speed since completion of training, but were still an average 0.08 m/s faster than before training. Author-noted limitations of the study included: they did not know if the training dosage was optimal for improving walking speed and distance; the focus was on walking rather than other aspects of walking (e.g., producing optimal kinematics); and most of the subjects used a wheelchair as their primary means of mobility so the amount of change qualified as meaningful change may be different from subjects who use other means of mobility; “the training parameters used in the robotic gait orthosis approach were configured to impose a kinematically appropriate gait pattern and stepping proceeded regardless of whether participants contributed effort;” and only ten people returned for longer follow-ups. Other limitations of the study include the small patient population, short-term follow-up, patients lost to follow-up, and the OG group had the largest number of patients who were less impaired.

Esnouf et al. (2010) conducted a randomized controlled trial to determine what impact FES (Odstock Dropped Foot Stimulator, Odstock Medical, Ltd., Salisbury, UK) would have on the activities of daily living in subjects with foot drop due to secondary progressive multiple sclerosis (n=64). Patients were randomized to physiotherapy exercises or to FES for 18 weeks. Subjects using an ankle-foot orthosis (AFO) at the beginning of the study continued to use it during the study. Follow-ups were conducted at weeks six, 12 and 18. The exercise group performed 30 minutes of exercises once or twice each day at home. The FES group used the Odstock device

for daily mobility. Using the Canadian Occupational Performance Measure, the exercise group reported a significant change in satisfaction at three months ( $p=0.0437$ ) and the FES group reported significant improvement in performance ( $p=0.0002$ ) and satisfaction ( $p=0.0437$ ). Compared to the exercise group, significant improvements in performance and satisfaction scores were reported in the FES group ( $p<0.05$ , each). The median number of self-reported falls during the study were five in the FES group and 18 in the exercise group ( $p=0.036$ ). Limitations of the study include the small patient population, short-term follow-up, heterogeneity of patient-reported problems, a greater number of patients in the exercise group wore ankle-foot orthosis or had rejected an AFO, and the number of patients lost to follow-up ( $n=11$ ).

Nooijen et al. (2009) conducted a randomized controlled trial ( $n=51$ ) to compare changes in gait quality with four body weight supported locomotor training (BWSLT) regimens, including: treadmill with manual assistance (TM) ( $n=13$ ), treadmill with peroneal nerve electrical stimulation (TS) (Digitimer) ( $n=15$ ), overground with peroneal nerve electrical stimulation (OG) ( $n=11$ ) (WalkAide2™), and treadmill with locomotor robot (LR) ( $n=12$ ). Subjects had chronic motor-incomplete spinal cord injuries. A mean 50 training sessions were completed by subjects over a 12 week period. All subjects walked with a higher cadence and had longer step and stride lengths following training with no significant differences between the groups. On completion of training, compared to baseline, the gait quality measures of the subjects were similar to 10 healthy subjects. For all groups, a significant increase was seen in cadence ( $p<0.01$ ) and step length and stride length of the stronger ( $p<0.01$ , each) and weaker leg ( $p<0.01$ , each). Step and stride length improved least in the LR group. Regarding interaction effects, the OG group had a significantly larger gain than the LR group in step length of the stronger leg ( $p=0.01$ ) and stride length of the weaker leg ( $p=0.04$ ). Compared to the LR group, the TS group had a significant gain in step length of the weaker leg ( $p=0.02$ ). Limitations of the study include the small patient population, short-term follow-up and incomplete data on 24 subjects from various outcome measures (i.e., TM,  $n=6$ ; TS,  $n=7$ ; OG,  $n=7$ , LR,  $n=4$ ).

Everaert et al. (2010) conducted a study on a subgroup ( $n=36$ ) of the Stein et al. (2010) patient population to “determine the effect of long-term use of a foot-drop stimulator [Walkaide] on residual corticospinal connections in people with central nervous system disorders.” Patients with nonprogressive ( $n=10$ ) and progressive ( $n=26$ ) disorders used FES for 3–12 months. The nonprogressive and progressive groups had a significant increase in mean-rectified MEP<sub>max</sub> (motor-evoked potentials) following FES ( $p=0.003$  and  $p=0.046$ , respectively). The MEP latencies were significantly smaller for the nonprogressive group than the progressive group ( $p=0.02$ ). The mean increases in maximum voluntary contraction (MVC) following FES were significantly different in the nonprogressive group ( $p=0.008$ ) and the progressive group ( $p=0.013$ ), but not significantly different between the two groups. The mean increases in MVC following FES were also significantly different in the nonprogressive group ( $p=0.008$ ) and the progressive group ( $p=0.013$ ) and not significantly different between the two groups. There was a significant positive correlation between MEP<sub>max</sub> changes and MVC changes ( $p<0.001$ ) indicating that those with greater increases in MEP<sub>max</sub> after WalkAide use also had greater increases in MVC. There was a significant improvement in walking speed following FES in the nonprogressive group ( $p=0.008$ ) and the progressive group ( $p=0.014$ ). The negative mean change in PCI indicated that the patients were walking with less effort following FES. The increases in MVC and MEP indicated that the patients had better voluntary control over the tibialis anterior muscle. Limitations of the study include the small patient population, short-term follow-up and lack of a control group.

In a multicenter nonrandomized prospective study, Stein et al. (2010) compared the orthotic and therapeutic effects of FES (WalkAide; Innovative Neurotronics, Austin, TX) on straight line and figure-8 walking performance of patients with chronic nonprogressive (i.e., stroke, spinal cord injury, head injury, cerebral palsy) ( $n=41$ ) and progressive (i.e., secondary progressive multiple sclerosis, familial spastic paraparesis) ( $n=32$ ) disorders resulting in foot drop. The patients were tested with FES on and off (orthotic effect) and before and after (therapeutic effect) use. Follow-up ranged from 3–11 months. At the three-month follow-up, both groups had a significant similar orthotic ( $p<0.03$ ) and therapeutic effect ( $p<0.005$ ) on figure-8 walking speed. Overall, the physiological cost index (PCI) (i.e., difference in resting and active heart rate) showed a decreasing trend ( $p=0.031$ ). At 11 months, the overall therapeutic effect was significant for the nonprogressive group ( $n=13$ ) ( $p<0.001$ ) and the progressive group ( $n=18$ ) ( $p=0.021$ ). The PCI significantly decreased over time in the nonprogressive group ( $p=0.039$ ), but not in the progressive group. The nonprogressive group continued to increase speed with and without FES compared to the progressive group who reached a plateau of gait speed with a tendency to a decline in speed. There was a significant difference in the use of the WalkAide by the

progressive group compared to the nonprogressive group ( $p=0.037$ ). Limitations of the study include the small heterogeneous patient population, short-term follow-up, and lack of randomization and a control group.

Barrett et al. (2009) randomly assigned 20 secondary progressive multiple sclerosis (SPMS) patients to FES (Odstock Dropped Foot Stimulator) and 24 MS patients to home exercise program to evaluate the effects of FES on walking performance. Patients had a predominantly unilateral dropped foot that was impairing mobility. Patients began with short walks the first two weeks and were then allowed to walk as tolerated. The FES settings were adjusted as needed for each individual throughout the study period. Follow-up occurred at six, 12 and 18 weeks. Statistically significant improvements in the 10 meter (m) walking speed and distance walked in three minutes were seen in the exercise group compared to no significant improvement in the FES group ( $p=0.028$ ). Otherwise, there were no significant differences between the groups. There were no mean changes from baseline and 18-week outcomes within the FES group compared to a significant increase in both walking over 10 m ( $p=0.0001$ ) and distance walked in three minutes ( $p=0.005$ ) in the exercise group. Within the FES group, there was a significant increase in mean values for 10 m walking speed and distance in three minutes with stimulation compared to no stimulation. Limitations of the study as noted by the authors included: the small patient population, patient fatigue that resulted in reduced walking time from six to three minutes, no baseline walking analysis, the drop out rate, and the inability to generalize the results due to the SPMS drop foot diagnosis of this MS group.

Hausdorff and Ring (2008) reported on the effects of the NESS L300 neuroprosthesis on the gait of 24 patients with chronic hemiparesis ( $5.8 \pm 5.2$  years) from stroke or traumatic brain injury whose walking was impaired by foot drop. In random order, the patients walked for six minutes while wearing force-sensitive insoles once with and once without the neuroprosthesis. Patients were evaluated again at four and eight weeks. Outcome measures included walking speed, swing, and stride time as well as a gait symmetry index and stride time variability. Significant improvement from baseline was noted for all measures at all follow-up timeframes. According to the authors, the use of FES for the correction of foot drop is not common and may be due to insufficient evidence and the ergonomic and technical problems associated with the FES systems. The study is limited by the small sample size and lack of comparison to standard treatment.

In a non-randomized comparative trial, Postans et al. (2004) reported the outcomes ( $n=14$ ) of partial weight-bearing (PWB) supported treadmill gait training augmented by a customized FES device in subjects with acute incomplete SCIs. The subjects, with American Spinal Injury Association class C or D injuries, participated in training that consisted of treadmill walking with PWB support augmented by FES. The study included walking on the treadmill for up to 25 minutes a day, five days a week, for four weeks. The intervention was compared to a four-week control period during which standard physical therapy (PT) was given. The authors reported a greater increase in overground walking endurance achieved after FES compared to after standard PT. A similar pattern was observed for overground walking speed.

In a prospective uncontrolled study ( $n=14$ ), Ladouceur et al. (2000) evaluated an FES orthosis for correction of gait disorder with incomplete SCI. All patients were enabled to ambulate assisted by FES surface electrodes. Patients were trained in FES for four weeks and encouraged to use FES as much as possible. At final follow-up, maximal therapeutic walking speed had increased 0.25 m/sec ( $p<0.005$ ) and maximal combined walking speed had increased 0.26 m/sec ( $p<0.002$ ) compared to baseline.

**Range Of Motion And Function In Patients With Upper Limb Paralysis Or Hemiplegia:** Koyuncu et al. (2010) conducted a randomized controlled trial to evaluate FES for the treatment of 50 hemiplegic patients with shoulder subluxation and pain. All patients received conventional rehabilitation and the study group also received FES stimulation (specific device not mentioned) to the supraspinatus and posterior deltoid muscles on the hemiplegic side, five times a day, one hour each for four weeks. There was a statistically significant decrease in pain during resting and passive range of motion (PROM) in the control group ( $p<0.05$ ) but not in the study group. Following therapy, radiographic analysis showed a significant improvement in shoulder subluxation and subluxation levels ( $p<0.001$ ,  $p<0.05$  respectively) in the study group but not in the control group. There were no significant differences in the pre- and post-rehabilitation resting and PROM VAS or active ROM between the groups. Limitations of the study include the small patient population and short-term follow-up.

**Other Indications:** Sbruzzi et al. (2010) conducted a systematic review and meta-analysis of randomized controlled trials to evaluate FES (device not given) for the treatment of patients with chronic heart failure (CHF).

The aim of the study “was to systematically review the effect of treatment with FES compared with conventional aerobic exercise training (CA) or control group in patients with CHF.” FES has been proposed as an alternative for patients unable to engage in conventional exercise therapy to improve functional capacity and prognosis of this population. Seven studies (n=224) met inclusion criteria. FES was applied to muscles in both legs for 30–60 minutes per day for 5–10 weeks. FES was compared to conventional aerobic exercise (CA) (n= 5 studies) or to a control group, no FES (n=2 studies). FES resulted in a small gain in peak oxygen consumption (VO<sub>2</sub>) and an increase in peak VO<sub>2</sub> of 2.78 milliliters of oxygen per kilogram (ml/kg) per minute, distance of the 6-minute walk test and muscle strength. However, the differences in muscle strength and distance of the 6-minute walk test were not significant. There was insufficient data to conduct a meta-analysis. Limitations of the analysis included the poor methodology of the studies, small patient populations and short-term follow-up.

**Professional Societies/Organizations:** The National Institute for Health and Clinical Excellence (NICE) (United Kingdom) (2009) published a guidance document on FES for foot drop of central neurological origin and stated that the evidence on safety and efficacy “appears adequate to support” the use of FES for foot drop in terms of improving gait, but the efficacy as it relates to quality of life and activities of daily living needs to be further investigated.

### **H-Wave Electrical Stimulation**

The H-WAVE electrical stimulation device generates a biphasic, exponentially decaying waveform with pulse-wide widths. Its waveform distinguishes it from TENS and other forms of electrical stimulators. H-WAVE is classified as a powered muscle stimulator. The large pulse width theoretically enables contraction in the muscle for extended periods of time at a low fatigue rate and increases circulation, muscle relaxation, pain relief and wound healing. H-wave stimulation has been used in the treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy. H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography. H-wave devices are available for self-administered home therapy.

**U.S. Food and Drug Administration (FDA):** The H-WAVE<sup>®</sup> Muscle Stimulator (Electronic Waveform Laboratory, Inc., Huntington Beach, CA) is FDA 510(k) approved is a class II device.

**Literature Review:** There is insufficient evidence in the published peer reviewed scientific literature to support the safety and effectiveness of the H-Wave electrical stimulators.

Blum et al. (2009) conducted a double-blind randomized controlled trial (n=22) to assess H-wave stimulation (H-Wave) in patients who had undergone open-reduction rotator cuff reconstruction. Twelve patients were randomized to H-wave and ten to sham therapy. Starting the day of surgery, patients used the device for one hour, twice a day, for 90 days. Physical therapy was initiated eight weeks following surgery. Patients treated with H-wave advanced more quickly with physical therapy. Ninety days following surgery the H-wave group had a loss of 11.67 degrees (p=0.007) in external rotation (arm at side) and the placebo group had a loss of 21.65 (p=0.007). Regarding internal rotation (arm at 90 degrees), the H-wave group had a loss of 13.33 degrees (p=0.006) compared to a loss of 23.25 degrees (p=0.0062) in the placebo group. No statistical differences were seen in all other range of motions. Limitations of this study include the small patient population and short-term follow-up.

Blum et al. (2008) conducted a systematic review and meta-analysis of randomized and nonrandomized controlled trials to evaluate the safety and efficacy of H-wave therapy. Five studies (n=6535) met inclusion criteria. H-wave was shown to decrease pain across various chronic soft tissue inflammation and neuropathic pain conditions, decrease pain medication intake (n=2 studies) and increase functionality (n=2 studies). However, author-noted limitations of the studies included the heterogeneity of the studies, inconsistency of the effects (e.g., reduction in pain medication, functionality), data were obtained from cross-sectional studies, data were subjective in nature (i.e., there were no formal examination findings, test results and/or laboratory values), various outcome measures, potential selection bias of publications for this review, and due to a lack of reported data it was not possible to statistically evaluate the safety of the therapy. Additional studies and “rigorous, controlled research” are needed to validate the proposed efficacy of H-Wave therapy.

In a technology assessment evaluating the use of H-wave for pain management, ECRI (2009) concluded that due to a lack of comparative effectiveness data it was not possible to determine how the efficacy of H-wave

compared to other therapies. A search of 22 databases provided two randomized controlled trials (n=54) that met inclusion criteria, and although a statistically significant advantage overall was indicated, the difference was not large enough to be clinically significant.

**Professional Societies/Organizations:** The Work Loss Data Institute (2009) stated that H-wave therapy may be considered on a one-month trial basis as an adjunct to an “evidence-based functional restoration” program for the treatment of diabetic neuropathic pain or chronic soft tissue inflammation. Its use should only be considered following failure of conservative care (e.g., pharmacotherapy, physical therapy, TENS).

### **High Voltage Galvanic Stimulation (HVG)**

Galvanic stimulation is characterized by high voltage pulsed stimulation and is proposed 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. The high voltage and direct current used in HVG differentiates it from the low voltage and alternating current used in TENS or NMES (Medi-Stem, 2011).

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

**Literature Review:** The few studies that were identified in the literature that addressed HVG were primarily randomized clinical trials and case comparisons published prior to 1997 with small patient populations and short-term follow-up. Patient selection criteria were lacking. There is insufficient evidence in the published peer reviewed scientific literature to support the safety and efficacy of HVG stimulation.

### **Interferential Therapy (IFT)**

IFT, also known as interferential stimulation (IFS), is a treatment modality that is proposed to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. Two medium-frequency, pulsed currents are delivered via electrodes placed on the skin over the targeted area producing a low-frequency current. IFT delivers a crisscross current at 4000–4150 pulses per second resulting in deeper muscle penetration. These features are proposed to provide more effective pain control compared to TENS with less pain. It is theorized that IFT prompts the body to secrete endorphins and other natural painkillers and stimulates parasympathetic nerve fibers to increase blood flow and reduce edema.

**U.S. Food and Drug Administration (FDA):** Interferential stimulator instruments are approved as 510(k) Class II devices. Examples of FDA-approved devices include the RSJ, RS JC (RS Medical, Vancouver, WA), IF 8000 (Biomotion, Madison, AL), RS-4i™ (RS Medical, Vancouver, WA), Flex-IT™ (EMSI, Alexander, VA).

**Literature Review:** The evidence in the published peer reviewed scientific literature does not support the safety and effectiveness of IFT for the treatment of multiple conditions including: constipation, urinary incontinence, pain associated with musculoskeletal disorders or injuries, osteoarthritis, stimulation of soft tissue healing, and stimulation of bone fracture healing.

**Musculoskeletal Pain:** The California Technology Assessment Forum (2005) evaluated the literature on IFT for the treatment of musculoskeletal pain and concluded that this treatment modality has not been shown to be as beneficial as alternative treatments such as nonsteroidal anti-inflammatory drugs and exercise therapy. Although IFT was found to be a generally safe technique, it did not meet the CTAF technology assessment criteria for the treatment of musculoskeletal pain.

In randomized controlled trials, Minder et al. (2003) (n=40) found IFT to have no overall beneficial effect on delayed-onset muscle soreness. In contrast, Jarit et al. (2003) (n=87) found that home IFT therapy may help to reduce pain and swelling in individuals who undergo knee surgery, and Hou et al. (2002) (n=119) reported that IFT may have benefit for relieving myofascial pain when used in conjunction with hot packs and range-of-motion exercises.

**Osteoarthritis:** Rutjes et al. (2009) conducted a systematic review of randomized or quasi-randomized controlled trials of electrical stimulation, including IFT (n=4 studies), for the treatment of osteoarthritis of the

knee. Due to the poor methodological and reporting quality of the studies, the effectiveness of IFT could not be confirmed.

**Urinary Incontinence:** In a randomized controlled trial, Demirturk et al. (2008) compared IFT (n=20) to Kegel exercises using a biofeedback device (n=20) for the treatment of urinary stress incontinence in women. Treatments lasted 15 minutes per session, three times a week, for 15 sessions. Outcome criteria included pelvic floor muscle strength, one-hour pad test and quality of life questionnaire. Following treatment, all parameters improved significantly ( $p < 0.5$  each) in each group. There were no significant differences in outcomes between the two groups. No adverse events were reported.

**Professional Societies/Organizations:** Regarding IFT, the Work Loss Data Institute (2009) stated that “there is no quality evidence of effectiveness except in conjunction with recommended treatments, including return to work, exercise and medications” and the evidence of improvement was limited. The reported results from trials were negative or non-interpretable and study design and methodology were poor. There was a lack of standardized protocol for IFT, and the therapies varied in electrode-placement technique, frequency of stimulation, pulse duration, and treatment time.

Following a systematic review of randomized controlled trials of 17 nonpharmacologic therapies for low back pain, the American Pain Society and the American College of Physicians (2007) stated that there was a limited number of studies available on IFT, and there were no clear differences between the use of IFT and spinal manipulation or traction for subacute or chronic back pain (Chou and Huffman, 2007).

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

MENS involves the use of a device that delivers small amounts of electrical current (millionths of an amp) to help relieve pain and heal soft tissues of the body. The application of microcurrent stimulation to an injured area is proposed to realign the body's electrical current and increase the production of adenosine triphosphate, resulting in increased healing and recovery and blocking of perceived pain. The electrical current is subsensory and usually not felt. MENS differs from TENS in that it uses a significantly reduced electrical stimulation (i.e., 1000 times less current than TENS). The goal of TENS is to block pain, while MENS acts on naturally-occurring electrical impulses to decrease pain by stimulating the healing process (Frequency Specific Microcurrent, 2011).

Frequency specific microcurrent (FSM) is a type of microcurrent therapy. The microcurrent device has two separate channels that allow both the frequency and current to be set independently for each channel. FSM is proposed as a treatment option for nerve and muscle pain, shingles, and herpes (Frequency Specific Microcurrent, 2011).

**U.S. Food and Drug Administration (FDA):** The FDA categorizes microcurrent devices 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) is 510(k) FDA approved as a class II device equivalent to predicate TENS devices.

**Literature Review:** There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and effectiveness of MENS including FSM. Rajpurohit et al. (2010) conducted a randomized controlled trial to compare the effectiveness of TENS (n=30) to MENS (n=30) on masticatory muscle pain secondary to bruxism (i.e., teeth grinding, clenching, clamping). Patients were treated for seven days. Compared to the TENS group, the MENS group experienced a significant improvement in the Visual Analog Scale (VAS) scores ( $p \leq 0.0001$ ) and tenderness ( $p \leq 0.001$ ). Limitations of the study include the small patient population, short-term follow-up, and inclusion of patients who had previously been treated with TENS or MENS.

Zuim et al. (2006) compared four groups of patients (n=5 patients per group) with temporomandibular disorders who were treated with MENS and/or occlusal splint therapy. Group 1 was treated with MENS plus splint. Group 2 was treated with placebo MENS plus splint. Group 3 was treated with MENS only, and group 4 was treated with placebo MENS. Although there was a reduction of pain in all groups, there were no statistical differences between the four groups or between MENS and occlusal splint therapy.

**Pelvic Floor Electrical Stimulation (PFES):** Although the exact mechanism is not fully understood, it is postulated that electrical stimulation of the bladder floor 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.

**U.S. Food and Drug Administration (FDA):** All devices with surface electrodes used for bladder stimulation are Class II devices. Examples of FDA 510(k) approved, nonimplantable electrical stimulators include the Detrusan<sup>®</sup> 500 (Innovamed USA, Inc., Lehigh Acres, FL) and the Pathway<sup>™</sup> CTS 2000 (Prometheus Group, Duxbury, MA).

**Literature Review:** There is insufficient evidence in the published peer-reviewed scientific literature to support electrical bladder stimulation for the treatment of urinary incontinence. Yamanishi et al. (2010) conducted a randomized controlled trial (n=56) to evaluate PFES in men with severe urinary incontinence (i.e., more than 200 grams per day) following radical prostatectomy. Thirty patients were randomized to sham therapy and 26 to PFES (i.e., anal probe for 15 minutes, twice daily). Follow-up occurred at one, three, six and 12 months. There was a significant difference in the number of patients in the treatment group who were continent at the one, three and six month follow ups (p=0.0161, p=0.0021 and p=0.0156, respectively) compared to the sham group. However, the effect after six months was “slight” and there was no significant difference at 12 months. The time to achieve continence was significantly shorter in the treatment group (p=0.0006). There were no significant differences in the changes in the amount of leakage, the International Consultation on Incontinence Questionnaire-Short Form scores and the King’s Health Questionnaire scores at twelve months. Limitations of the study include the small patient population and short-term follow-up.

In a Cochrane review of conservative management for post-prostatectomy urinary incontinence, Hunter et al. (2007) reported that “analysis of other conservative interventions such as transcutaneous electrical nerve stimulation and anal electrical stimulation, or combinations of these interventions were inconclusive. There were too few data to determine treatment effects on incontinence after TURP. The findings should continue to be treated with caution, as most studies were of poor to moderate quality.”

In a randomized controlled trial, Goode et al. (2003) studied the effect of behavioral training with and without PFES on stress incontinence in 200 women. 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. The authors noted that there is no current consensus regarding the efficacy of bladder stimulation and clear patient selection criteria are not available.

The California Technology Assessment Forum (2004) reviewed the evidence on 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 authors found insufficient evidence to conclude that PFES is as beneficial as behavioral or pharmacological therapies.

**Professional Societies/Organizations:** In a guidance document on the management of urinary incontinence in women, the National Institute for Health and Clinical Excellence (NICE, 2006) (United Kingdom) recommended that electrical stimulation not be routinely used in the treatment of women with overactive bladder or be used in combination with pelvic floor muscle training. “While there is no evidence of effectiveness for electrical stimulation” the consensus of the Guideline Development Group was that electrical stimulation may be considered to aid motivation and adherence to therapy in women who cannot actively contract pelvic floor muscles.

**Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT):** PENS involves the delivery of an electrical current through the insertion of a needle below the skin. PENS is similar to TENS except that the needles are inserted one to four centimeters around or adjacent to the applicable nerve. PENS is generally reserved for patients who fail to obtain pain relief from TENS.

PNT is a variation of PENS which was 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 to stimulate nerve fibers in the

deep tissues. 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 granted marketing approval by the FDA via the 510(k) process. 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 also received 510(k) approval.

**Literature Review:** There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of PENS or PNT as a treatment option for chronic pain. Weiner et al. (2008) conducted a randomized controlled trial (n=200) to evaluate the efficacy of PENS in adults with chronic low back pain. Patients were randomized to either 1) PENS, 2) brief electrical stimulation to control for treatment expectance (control-PENS), 3) PENS plus general conditioning and aerobic exercise (GCAE) or to 4) control-PENS plus GCAE. Treatment was delivered twice a week for six weeks to the 50 participants in each group. All groups reported significantly reduced pain (McGill Pain Questionnaire short form) and disability and improved gait velocity, which was sustained at six months. Significantly fewer fear avoidance beliefs were reported in the CGAE group compared to the non-CGAE group. Comparable reduced pain and function were reported by the PENS and control-PENS group, whether delivered for five minutes or 30 minutes. Thus, the exact dose of electrical stimulation needed for analgesia could not be determined. PENS and GCAE were more effective than PENS alone in reducing fear avoidance beliefs, but not in reducing pain or in improving physical function. There was a statistically significant improvement in chair rise time in the control-PENS plus CGAE compared to control-PENS alone. The overall drop-out rate was 8%.

Kang et al. (2007) conducted a single-blinded, randomized study of 63 patients with knee pain secondary to osteoarthritis. Twenty-eight patients were randomly assigned to the sham group and 35 to the live treatment group. The study investigated the efficacy of PNT in reducing knee pain and medication consumption during the first week following treatment. Pain levels were rated on a 100-mm visual analog pain scale. The live group had greater efficacy than the sham group in all time periods; however, only in the immediate post-treatment period did it reach statistical significance (p=0.0361). The overall median pain intensity difference over all periods was 14.5 for the live group and 6.5 for the sham group and reached statistical significance (p=0.0071). At one week follow-up, the live group reported significantly less medication use (p<0.0001) than the sham group.

A Hayes report (2006) on the Vertis PNT system for the treatment of low back pain (LBP) examined four randomized crossover trials (n=34–75). 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 suggested 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 is insufficient to support its use.

**Professional Societies/Organizations:** The Work Loss Data Institute (2009) stated that there is a “lack of high quality evidence to prove long-term efficacy” of the use of PENS. They stated that PENS may be considered as an adjunct to an “evidence-based functional restoration” program after all other non-surgical treatments have been tried, failed, or are unsuitable or contraindicate (e.g., exercises, TENS).

**Peripheral/Posterior Tibial Nerve Stimulation (PTNS):** PTNS, also called peripheral tibial nerve stimulation or percutaneous tibial nerve stimulation, is electrical stimulation of the posterior tibial nerve proposed as a treatment option for voiding dysfunctions including frequency, urgency and urge incontinence and for fecal incontinence. PTNS involves neuromodulation of the sacral nerve which is thought to inhibit bladder instability. A low voltage current is applied for 30 minutes, 1-3 times per week, for 12 weeks. If effective, maintenance sessions are recommended every two to three weeks.

**U.S. Food and Drug Administration (FDA):** The Urgent<sup>®</sup> PC Neuromodulation System (Uroplasty, Inc., Minneapolis, MN) was granted marketing approval by the FDA via the 510(k) process. 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:** PTNS has been proposed for the treatment of urological disorders including urinary incontinence, overactive bladder, pelvic floor dysfunction, chronic prostatitis and fecal incontinence. There is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of PTNS. Studies primarily include small patient populations and short-term follow-ups with self-reported outcomes and conflicting results. Patient selection criteria and treatment protocol have not been established.

De Sèze et al. (2011) conducted a multicenter (n=5), prospective case series to investigate the efficacy of PTNS in adult multiple sclerosis patients (n=70) with overactive bladder syndrome refractory to oral anticholinergics. A total of 66 patients performed self-administered, 20-minute daily PTNS sessions. Follow-up occurred at days 30 and 90. The primary outcome was the “clinical efficacy on urgency, based on warning time (WT), the urgency Mesure du Handicap Urinaire (MHU) subscale and frequency based on a three-day voiding chart.” The secondary outcomes were the “clinical efficacy on continence and quality of life, urodynamic parameter changes and tolerance.” At the 30-day follow-up, 82.6 % of patient experienced a significant improvement in the primary outcome. There was a significant decrease in severe urgency in 51.3% of the patients (P<0.002) and urgency MHU score (P<0.01) and an increase in the WT (P<0.001). A significant improvement was seen in frequency in 67% of patients (P<0.001), decrease of frequency prevalence (P<0.02), and an improvement of frequency MHU sub-score (P<0.008). Significant improvements of secondary outcome measurements included: improvement in continence in 62% of the patients (P<0.001) and complete continence in 44.9% of patients. Psychosocial burden and quality of life were also significantly improved (P<0.001, each). Improvements in primary outcomes were sustained and seen in 83.3% of patients at the 90-day follow-up. There were no significant changes on detrusor pressures and bladder compliance. The intergroup analysis showed no significant differences between the responders and nonresponders regarding the primary and secondary outcome and patients who were under self-intermittent catheterization remained so. At the end of the study 76.6% of responders (n=36) and 66.7% of non responders (n=44) chose to continue PTNS. Limitations of the study include the small patient population, short-term follow-up and lack of a control group and randomization.

Finazzi-Agrò (2010) conducted a randomized controlled trial (n=35) to evaluate the efficacy of PTNS in women with detrusor overactivity incontinence who did not respond to antimuscarinic therapy. The PTNS group (n=18) was treated with 30-minute sessions three times per week, for 12 weeks, and the control group (n=17) received sham stimulation. At baseline and at the 12-week follow-up patients completed a three-day voiding diary which included the number of incontinence episodes, number of micturitions, voided volumes and incontinence quality of life (I-QoL) score. Seventeen patients (71%) in the PTNS group and none in the placebo group (p<0.001) were considered responders (i.e., 50% or greater reduction in urge incontinence episodes). A significant improvement in the number of incontinence episodes, voided volume and I-QoL score (p<0.001, each) was reported in the PTNS group but not in the control group. Limitations of the study include the small patient population, short-term follow-up, and 10% dropout rate.

Schreiner et al. (2010) conducted a randomized controlled trial to evaluate the efficacy of PTNS for the treatment of urinary urge incontinence in 52 women, age ≥ 60 years. The women were randomly assigned to PTNS plus standard therapy (Kegel exercises and bladder training) or standard therapy alone (n=25, each). Following 12-weeks of treatment, the PTNS group showed significant improvement in daytime urinary frequency (p=0.003), nocturia (p<0.001), number of urge urinary incontinence episodes (p<0.001) and average score on the International Incontinence questionnaire (p<0.001). The treatment group also showed significant improvement (p<0.05) on the King Health Questionnaire (i.e., impact of urinary incontinence, limitations of daily activities, physical limitations, emotions, sleep/provision and measures of severity). The control group showed a significant improvement in number of stress urinary incontinence episodes (p=0.005) and urge incontinence episodes (p<0.001). Significantly fewer patients continued to have urge urinary incontinence in the PTNS group (p=0.007). There was a significant difference between the groups in nocturia (p<0.001) and number of urge incontinence episodes (P<0.001) but not in the other outcome measures. Limitations of the study include the small patient population, the short-term follow-up, lack of sham therapy in the control group and lack of generalizability of the study.

Yoong et al. (2010) reported on a 6-week case series of 43 women with overactive bladder syndrome unresponsive to anticholinergics and bladder retraining. Patients underwent six weekly, 30-minute PTNS

sessions. A positive response rate was reported in 69.7% of patients. Significant results were reported in median daytime and nocturnal frequency, urge leak episodes and number of pads ( $p < 0.05$ , each). A 25% improvement in Incontinence Impact Questionnaire scores was also reported. Limitations of the study include the small patient population, short-term follow-up, self-reported outcomes and lack of a control group and randomization.

In a multicenter, randomized controlled trial (i.e., the Study of Urgent<sup>®</sup> PC vs. Sham Effectiveness in Treatment of Overactive Bladder Symptoms [SUMiT]), Peters et al. (2010) compared the efficacy of PTNS ( $n=110$ ) to inactive sham therapy ( $n=110$ ) in patients with overactive bladder symptoms. Patients received 30-minute sessions, once a week, for 12 weeks. At 13 weeks, patient responses on the global response assessment (GRA) showed a significant improvement in overall bladder symptoms and urinary frequency ( $p < 0.001$ , each) in the PTNS group compared to the sham group. Self-reported 3-day voiding diaries recorded statistically significant improvements in frequency, nighttime voids, voids with moderate to severe urgency and urinary urge incontinence episodes in the PTNS group. Significant improvements were reported in moderate to severe urgency and urge incontinence in the sham patients. Following PTNS, statistically significant improvements were seen on the condition specific OAB questionnaire (short form) symptom severity score and quality of life scores compared to sham. In the PTNS group statistically significant improvements were reported on the SF-36 general health survey quality of life in the physical ( $p=0.002$ ) and mental domain scales. ( $p=0.049$ ). PTNS adverse events included ankle bruising, needles site discomfort and bleeding, and tingling in the leg. No sham adverse events were reported. A limitation of the study is the short-term follow-up.

Peters et al. (2009) conducted a randomized controlled trial (i.e., the Overactive Bladder Innovative Therapy trial [OrBIT]) to compare the effectiveness of PTNS (Urgent PC) ( $n=50$ ) to extended-release tolterodine ( $n=50$ ) for the treatment of overactive bladder with or without a history of anticholinergic drug use. PTNS treatments were delivered for 30 minutes, once per week, for 12 weeks. Tolterodine patients received 4 milligrams (mg) daily with a subsequent decrease to 2 mg if intolerability occurred ( $n=2$ ). Follow-up was conducted face-to-face with PTNS patients and by phone for tolterodine patients. A statistically significant improvement or cure in the PTNS group compared to the tolterodine group was reported by patient assessment ( $p=0.01$ ) but was not significant when reported by the investigators ( $p=0.05$ ). Significant improvements in overactive bladder symptom episodes were reported from baseline to 12 weeks in both groups, but the differences between the two groups were not significant. The mean reduction in voids for 24 hours was not significant in either group. Although improvements were seen in OAB questionnaire results and quality of life scores in both groups, the differences between groups were not significant. No serious adverse events or device malfunctions were reported. Limitations of the study noted by the authors included no placebo in the tolterodine arm, no sham in the PTNS arm, and no blinding to treatment assignment. Sixteen patients did not complete the 12-week study.

MacDiarmid et al. (2010) reported the one-year outcome of 25 patients from the above Peters et al. (2010) OrBIT study who volunteered to continue with PTNS. Compared to baseline, the benefits at 12-weeks were sustained at one year as reported by the patients on the GRA and voiding diaries. Compared to baseline, significant mean improvements were seen in frequency decreased by 2.8 voids daily ( $p < 0.001$ ), daily urge incontinence episodes decreased by 1.6 ( $p < 0.001$ ), nocturia decreased by 0.8 voids ( $p < 0.05$ ), and voided volume improved by 39 cubic centimeters (cc) ( $p < 0.05$ ). Author noted limitations of the one-year follow-up study included "a potential placebo effect based on subject time spent with clinicians, no prescribed tapering schedule to evaluate when treatment effects fail, no cost analysis, and no device sham effect." It was also unknown if patients were counseled on fluid management and if or how fluid management habits may have influenced the results.

In a randomized controlled trial, Kabay et al. (2009) compared the efficacy of PTNS (Medtronic Keypoint<sup>®</sup> Net, Alpine Biomed Corp. Fountain Valley, CA) ( $n=45$ ) to sham therapy ( $n=44$ ) for the treatment of therapy-resistant category IIIB chronic non-bacterial prostatitis (i.e., chronic pelvic pain syndrome). Patients received a 30 minute treatment, once a week, for 12 weeks. Compared to baseline, the 12-week mean National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) scores, the mean Visual Analog Score (VAS) for pain, and the mean VAS for urgency significantly improved ( $p < 0.001$  each) in the PTNS group, but not in the sham group. Due to the small patient population and short-term follow-up, long-term randomized controlled trials with large patient populations are needed to support the outcomes of this study.

Kabay et al. (2009) conducted a case series to evaluate the acute effects of PTNS on urodynamic findings in patients (n=32) with Parkinson's disease. Patients had storage symptoms (e.g., urge incontinence, urgency, frequency), overactive bladder (OAB) and involuntary detrusor contraction (confirmed on routine cystometry). A significant improvement ( $p < 0.001$ ) was seen in the mean first involuntary detrusor (1st IDCV) recorded at baseline,  $145.2 \pm 41.1$  (55–265) milliliter (ml), compared to results during PTNS,  $244.7 \pm 51.7$  (145–390) ml. In 20 cases, increments of 50% in the 1<sup>st</sup> IDCV volume were seen during PTNS. A statistically significant improvement of 100 ml of maximum cystometric capacity was seen in 18 cases ( $p < 0.001$ ). Five of seven patients (71.4%) with pseudodyssnergia had complete relief of symptoms. The authors cautioned that the data should be verified in a prospective multicenter study before PTNS is introduced into routine clinical practice.

In a prospective observational study, Nuhoglu et al. (2006) investigated the efficacy of the UroSurge® Percutaneous Stoller Afferent Nerve Stimulator (SANS™) (Urosurge, Inc., Coralville, IA) 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. The early success rate was 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 decreased in about three months.

In a randomized controlled trial, Karademir et al. (2005) compared outcomes in patients after treatment with SANS alone (n=21) to 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 commented that combination with a low-dose anticholinergic increased the success rate of SANS without causing significant side effects.

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.

Govier et al. (2001) conducted a prospective multicenter clinical trial (n=53) to determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment of refractive 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.

In a technology assessment on PTNS, the BlueCross BlueShield Association (2011) concluded that the evidence in three randomized controlled trials established a short-term benefit for PTNS, but that the durability and long-term outcomes are unknown. There was insufficient evidence to permit conclusions regarding the effect on net health outcomes and/or whether PTNS is as beneficial as alternate treatment options.

**Professional Societies/Organizations:** In their recommendations on the management of urinary incontinence in women, NICE (2006) stated that “there is a need for a robust evaluation for PTNS for the treatment of urinary incontinence.” One 12-week randomized controlled trial (n=43), and two case series (n=103) with 1–3 weeks follow-up met inclusion criteria.

### **PrimaBella™ Nerve Stimulation Therapy**

PrimaBella (manufactured by Neurowave Medical Technologies, Chicago, IL and distributed by Alaven Pharmaceutical, LLC., Marietta, GA) nerve stimulation therapy, also called acustimulation or transcutaneous electrical acupoint stimulation, is proposed for the treatment of nausea and vomiting associated with pregnancy. The device is worn on the wrist, delivers intermittent electrical pulses to the Neiguan point (P6) sending signals via the median nerve to the emetic center in the brain. The stimulation is proposed to regulate the nausea signaling process between the brain and stomach resulting in normal stomach rhythm and relief of nausea and vomiting (Alaven Pharmaceutical, 2009).

**U.S. Food and Drug Administration (FDA):** PrimaBella is FDA approved as a 510(k) class II neuromodulation device approved for nausea and vomiting due to pregnancy (NVP). The original approval of this same device was the Reliefband NST Device (Woodside Biomedical, Inc., Lake Forest, CA).

**Literature Review:** There is insufficient evidence in the published peer-reviewed scientific literature to support the effectiveness of PrimaBella for the treatment of NVP. Rosen et al. (2003) conducted a randomized controlled trial with pregnant volunteers (n=187) to evaluate the effectiveness of acustimulation (ReliefBand now called PrimaBella) in relieving nausea and vomiting in pregnancy. Patients were 6–12 weeks' gestation and randomized to acustimulation (n=95) or sham stimulation (n=92). The device was worn for 21 days, and the patient kept a log of device usage and location, and occurrences of nausea and vomiting. The use of medications for nausea was not controlled during the study. The time-averaged change in the self-reported Rhodes Index of Nausea, Vomiting and Retching total experience was significantly better in the acustimulation group compared to the sham group (p=0.02). At the end of the 21-day trial, weight gain was significantly greater in the study group compared to the sham group (p=0.003). Occurrences of dehydration secondary to nausea and vomiting were significantly fewer in the acustimulation group compared to the sham group (p=0.013). There were no significant differences between the groups in medication usage or urinary ketones. The authors noted that the study "did not have sufficient power to assess whether efficacy of the device was related to gestational age at enrollment." Other limitations of the study include the short-term use of the device, and a drop out rate of 18.6%.

### **Threshold/Therapeutic Electrical Stimulation (TES)**

TES is the application of a low level current (2–10 milliamps) to the muscles in the body. It is typically applied at home while the patient is sleeping, for 8–12 hours per night, for up to six nights a week, for years. Researchers have proposed the use of TES for decreasing neuromuscular spasms that result from involuntary muscle contractions in patients with motor disorders (e.g., cerebral palsy, spina bifida). Proposed outcomes of TES include: improved muscle strength, decreased spasticity, increased joint mobility, and improved bowel and bladder dysfunction. It is also proposed as a treatment option for scoliosis.

**U.S. Food and Drug Administration (FDA):** TES devices are approved as 510(k) FDA Class II devices. The NT200-TES (Bio-Medical Research LTD, Laurel, MD) is an example of an approved device.

**Literature Review:** The exact mechanism by which threshold electrical stimulation (TES) might improve motor function in children with cerebral palsy or other motor disorders is unclear. Study results are conflicting regarding the potential benefit of TES. There is insufficient published peer-reviewed scientific literature to support TES in the treatment of cerebral palsy or other motor disorders.

Kerr et al. (2006) conducted a randomized, placebo-controlled trial to assess the efficacy of NMES and TES in strengthening quadriceps muscles of both legs in 60 children with cerebral palsy (CP) with diplegia. The children were randomized into one of three groups: NMES (n=18), TES (n=20), or placebo (n=22). Outcome measures included peak torque of the left and right quadriceps muscles, gross motor function, and impact of disability. They were assessed at baseline, at a six week follow-up visit, and at the end of treatment (16 weeks). No statistically significant difference was noted for NMES or TES versus placebo for strength or function. Statistically significant differences were noted between NMES and TES versus placebo for impact of disability at the end of treatment, but only between TES and placebo at the six week follow-up. The authors noted that further evidence is required to establish the role of NMES and TES as an adjunct therapy, to define patient populations that would benefit from NMES and TES and to determine the appropriate dosing parameters.

Dali et al. (2002) conducted a randomized controlled trial to determine whether a group of stable children with CP (i.e., 36 males, 21 females; mean age 10; age range 5–18) would improve their motor skills after 12 months of TES. Two-thirds received active and one-third received inactive stimulators. Tests were videotaped and assessed blindly to record qualitative changes that might not be reflected in performance measurements. Range of motion, degree of spasticity, and muscle growth measured by computed tomography (CT) were evaluated. Fifty-seven of 82 outpatients who were able to walk at least with a walker completed all 12 months of treatment (hemiplegia [n= 25]); diplegia [n= 32]). There was no significant difference between active and placebo treatment in any of the study groups. Visual and subjective assessments favored TES, whereas objective indices showed the opposite trend. The authors concluded that TES in these CP patients did not have any significant clinical effect during the test period and that additional studies are needed to establish whether or not TES causes improvement in children with other movement disorders than the children with hemiplegia and diplegia in this study.

**Summary**

Neuromuscular electrical stimulation (NMES) is an established therapy for the treatment of disuse atrophy when the nerve supply to the atrophied muscle is intact and NMES is used as one component of a comprehensive rehabilitation program.

Although there is limited evidence in the published peer-reviewed scientific literature to support transcutaneous electrical nerve stimulators (TENS) for the treatment of patients with chronic pain, TENS is an established treatment modality for this indication when conventional therapy has been tried for three months and failed. TENS is also supported for the treatment of pain in the immediate post-operative period following surgery (i.e. within 30 days of surgery). However, there is insufficient evidence in the published peer-reviewed scientific literature to support TENS for the treatment of acute and chronic headaches, abdominal pain, pelvic pain and temporomandibular joint (TMJ) pain. Studies investigating TENS for these conditions are lacking.

Conductive garments used in conjunction with TENS or NMES are appropriate when the patient has large areas or numbers of sites to be stimulated; 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.

Evidences also does not support electrical stimulation devices such as bioelectric nerve block (electroceutical therapy); cranial electrical stimulation (cranial electrotherapy stimulation); electrical sympathetic stimulation therapy; electro therapeutic point stimulation (ETPS<sup>SM</sup>); functional electrical stimulation (FES); H-WAVE electrical stimulation; high-voltage galvanic stimulation (HVG); interferential therapy (IFT), microcurrent electrical nerve stimulation (MENS), including frequency-specific microcurrent (FSM); pelvic floor electrical bladder stimulation (PFES); percutaneous electrical nerve stimulation (PENS); percutaneous neuromodulation therapy (PNT); peripheral/posterior tibial nerve stimulation (PTNS); PrimaBella<sup>™</sup> nerve stimulation therapy; and threshold/therapeutic electrical stimulation (TES). Overall, studies primarily included small, heterogeneous patient populations; short-term follow-ups; poor methodology; patient, self-reported outcomes; various outcome measures and treatment regimens; insufficient or conflicting data; high drop-out (e.g., 10%) and inconsistent results. Although some comparative studies reported significant intragroup improvements following stimulation, intergroup differences weren't significant. The clinical utility and beneficial impact on net health outcomes have not been established for these devices.

**Coding/Billing Information**

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

**Neuromuscular Electrical Stimulation (NMES)**

**Covered when medically necessary:**

HCPCS Codes	Description
E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive

	fibers separated from the patient's skin by layers of fabric)
E0745	Neuromuscular stimulator, electronic shock unit

ICD-9-CM Diagnosis Codes	Description
728.2	Muscular wasting and disuse atrophy, not elsewhere classified

### **Transcutaneous Electrical Nerve Stimulator (TENS)**

**Covered when medically necessary:**

HCPSC 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
337.20-337.29	Reflex sympathetic dystrophy
338.12	Acute post-thoracotomy pain
338.18	Other acute postoperative pain
338.21-338.29	Chronic pain
338.4	Chronic pain syndrome
353.0-353.9	Nerve root and plexus disorders
354.0-354.9	Mononeuritis of upper limb and mononeuritis multiplex
355.0-355.79	Mononeuritis of lower limb and unspecified site
356.0-356.9	Hereditary and idiopathic peripheral neuropathy
715.00-715.99	Osteoarthritis
717.7	Chondromalacia of patella
717.81-717.89	Other internal derangement of knee
717.9	Unspecified internal derangement of knee
719.40-719.49	Pain in joint
720.2	Sacroiliitis, not elsewhere classified
721.0-721.91	Spondylosis and allied disorders
722.0	Displacement of cervical intervertebral disc without myelopathy
722.10-722.11	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.4	Degeneration of cervical intervertebral disc
722.51-722.52	Degeneration of thoracic or lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.70-722.73	Intervertebral disc disorder with myelopathy
722.80-722.83	Postlaminectomy syndrome

722.90- 722.93	Other and unspecified disc disorder
723.0	Spinal stenosis in cervical region
723.1	Cervicalgia
723.2	Cervicocranial syndrome
723.3	Cervicobrachial syndrome (diffuse)
723.4	Brachial neuritis or radiculitis NOS
724.00- 724.09	Spinal stenosis, other than cervical
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.6	Disorders of sacrum
724.70- 724.79	Disorders of coccyx
724.9	Other unspecified back disorders
726.0	Adhesive capsulitis of shoulder
726.10- 726.19	Rotator cuff syndrome of shoulder and allied disorders
726.2	Other affections of shoulder region, not elsewhere classified
726.30- 726.39	Enthesopathy of elbow region
726.4	Enthesopathy of wrist and carpus
726.5	Enthesopathy of hip region
726.60- 726.69	Enthesopathy of knee
726.70- 726.79	Enthesopathy of ankle and tarsus
726.8	Other peripheral enthesopathies
726.90- 726.91	Unspecified enthesopathy
728.71	Plantar fascial fibromatosis
729.1	Myalgia and myositis, unspecified
729.2	Neuralgia, neuritis and radiculitis, unspecified
729.5	Pain in limb

**Experimental/Investigational/Not Covered:**

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
290.0-290.9	Dementias
291.2	Alcohol-induced persisting dementia
292.0	Drug withdrawal
292.82	Drug induced dementia
296.20- 296.26	Major depressive disorder, single episode
296.30- 296.36	Major depressive disorder, recurrent episode
300.00- 300.09	Anxiety states
303.00- 303.93	Alcohol dependence syndrome
304.00- 304.93	Drug dependence

307.40-307.49	Specific disorders of sleep of nonorganic origin
307.81	Tension headache
311	Depressive disorder, not elsewhere classified
314.01	Attention deficit disorder, with hyperactivity
331.0	Alzheimer's disease
331.11-331.19	Frontotemporal dementia
331.82	Dementia with Lewy bodies
338.3	Neoplasm related pain
339.00-339.89	Other headache syndromes
346.01-346.93	Migraine
388.30-388.32	Tinnitus
401.0-401.9	Essential hypertension
413.0-413.9	Angina pectoris
428.0-428.9	Heart failure
438.0-438.9	Late effects of cerebrovascular disease
493.00-493.92	Asthma
496	Chronic airway obstruction, not elsewhere classified
524.60-524.69	Temporomandibular joint disorders
564.00-564.09	Constipation
596.51	Hypertonicity of bladder
625.0	Dyspareunia
625.2	Mittelschmerz
625.3	Dysmenorrhea
625.5	Pelvic congestion syndrome
625.70-625.79	Vulvodynia
625.9	Unspecified symptom associated with female genital organs
643.00-643.93	Excessive vomiting in pregnancy
707.0-707.9	Chronic ulcer of skin
718.30-718.39	Recurrent dislocation of joint
718.70-718.79	Developmental dislocation of joint
719.00-719.99	Effusion of joint
723.5	Torticollis, unspecified
724.5	Backache, unspecified
724.8	Other symptoms referable to back
727.00-727.09	Synovitis and tenosynovitis
727.50-727.59	Rupture of synovium
727.60-727.69	Rupture of tendon, nontraumatic
728.2	Muscular wasting and disuse atrophy, not elsewhere classified
728.85	Spasm of muscle
735.0-735.9	Acquired deformities of toe

739.0-739.9	Nonallopathic lesions, not elsewhere classified
780.01	Coma
780.52	Insomnia, unspecified
781.0	Abnormal involuntary movements
781.2	Abnormality of gait
782.3	Edema
784.0	Headache
786.00-786.90	Dyspnea and respiratory abnormalities
787.2-787.29	Dysphagia
787.6	Incontinence of feces
788.30-788.39	Urinary incontinence
789.00-789.99	Abdominal pain
800.00-829.1	Fractures
836.0-836.59	Dislocation of knee
840.0-840.9	Sprains and strains of shoulders and upper arm
841.0-841.9	Sprains and strains of elbow and forearm
842.0-842.19	Sprains and strains of wrist and hand
843.0-843.9	Sprains and strains of hip and thigh
844.0-844.9	Sprains and strains of knee and leg
845.0-845.19	Sprains and strains of ankle and foot
846.0-846.9	Sprains and strains of sacroiliac region
847.0-847.9	Sprains and strains of other and unspecified parts of back
848.0-848.9	Other ill-defined sprains and strains
959.01-959.9	Injury, other and unspecified
994.6	Motion sickness
V11.3	Personal history of alcoholism
V76.51	Special screening for malignant neoplasms, colon
	All other codes

**Experimental/Investigational/Unproven/Not Covered when used to report PrimaBella™ nerve stimulation therapy:**

<b>HCPCS Codes</b>	<b>Description</b>
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
643.00-643.93	Excessive vomiting in pregnancy

**Miscellaneous Other Electrical Stimulation Devices**

**Experimental/Investigational/Unproven/Not Covered:**

<b>HCPCS Codes</b>	<b>Description</b>
E0740	Incontinence treatment system, pelvic floor stimulator, monitor, sensor and/or trainer
E0764	Functional neuromuscular stimulator, transcutaneous stimulation of muscles of ambulation with computer control, used for walking by spinal cord injured, entire

	system, after completion of training program
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified.
E1399†	Durable medical equipment, miscellaneous

†**Note: Not covered when used to report any electrical stimulator device indicated in this coverage policy as experimental, investigational or unproven.**

ICD-9-CM Diagnosis Codes	Description
	All codes

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	8/15/2008	0160	Electrical Stimulators
Great-West Healthcare	8/23/2007	07.355.01	Incontinence, Posterior Tibial Nerve Stimulation (PTNS)
	7/28/2006	04.239.02	Interferential Therapy
	1/23/2008	06.335.02	Percutaneous Neuromodulation Therapy (PNT)

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