

## Medical Policy



### Title: **Electrical Stimulation Devices for Home and Provider Use**

#### **Professional**

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Populations	Interventions	Comparators	Outcomes
<b>Transcutaneous Electrical Stimulation Devices (TENS) and Form Fitting Conductive Garment</b>			
Individuals: • With chronic pain	Interventions of interest are: • Transcutaneous electrical nerve stimulation	Comparators of interest are: • Physical therapy • Pharmacotherapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use
Individuals: • With acute pain	Interventions of interest are: • Transcutaneous electrical nerve stimulation	Comparators of interest are: • Pharmacotherapy	Relevant outcomes include: • Symptoms • Medication use

<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
<b>Electrostimulation and Electromagnetic Therapy</b>			
Individuals: • With any wound type (acute or nonhealing)	Interventions of interest are: • Electrostimulation • Electromagnetic therapy	Comparators of interest are: • Standard wound care	Relevant outcomes include: • Symptoms • Change in disease status • Morbid events • Quality of Life • Treatment-related morbidity
<b>Interferential Current Stimulation</b>			
Individuals: • With musculoskeletal conditions	Interventions of interest are: • Interferential current stimulation	Comparators of interest are: • Physical therapy • Medication • Different type of electrical stimulation	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With gastrointestinal disorders	Interventions of interest are: • Interferential current stimulation	Comparators of interest are: • Dietary changes • Medication • Different type of electrical stimulation	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With poststroke spasticity	Interventions of interest are: • Interferential current stimulation	Comparators of interest are: • Standard stroke rehabilitation	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
<b>Electrical Stimulation for the Treatment of Arthritis</b>			
Individuals: • With osteoarthritis	Interventions of interest are: • Electrical stimulation	Comparators of interest are: • Pharmacologic therapy • Physical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Treatment-related morbidity

## **DESCRIPTION**

- A. Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin at the site of pain. TENS may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic).

Transcutaneous electrical nerve stimulation (TENS) has been used to treat chronic intractable pain, postsurgical pain, and pain associated with active or post-trauma injury unresponsive to other standard pain therapies. It has been proposed that TENS may provide pain relief through the release of endorphins in addition to potential blockade of local pain pathways. TENS has also been used to treat dementia by altering neurotransmitter activity and increasing brain activity that is thought to reduce neural degeneration and stimulate regenerative processes. Percutaneous electrical nerve stimulation (PENS) is similar to TENS but uses microneedles that penetrate the skin instead of surface electrodes.

**Regulatory Status**

TENS devices consist of an electrical pulse generator, usually battery-operated, connected by wire to 2 or more electrodes, which are applied to the surface of the skin at the site of the pain. Since 1977, a large number of devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Marketing clearance via the 510(k) process does not require data regarding clinical efficacy; these devices are considered substantially equivalent to predicate devices marketed in interstate commerce prior to May 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified and do not require approval of a premarket approval application (PMA). FDA product code: GZJ.

In 2014, the Cefaly® (STX-Med, Herstal, Belgium), which is a TENS device, was granted a de novo 510(k) classification by FDA for the prophylactic treatment of migraine in patients 18 years of age or older.<sup>1</sup> FDA product code: PCC.

- B. Form Fitting Conductive Garment – Is a garment with conductive fibers which are separated from the patients' skin by layers of fabric used for delivering TENS and NMES.
- C. Neuromuscular Electrical Stimulation Devices (NMES) - Attempts to stimulate motor nerves to cause contraction of muscles rather than alter the perception of pain. NMES are used to prevent disuse atrophy, relax muscle spasm, increase blood circulation, improve range of motion and re-educate muscles.
- D. Interferential Therapy (such as the Medstar™ 100 and the RS-4i) - Interferential current stimulation (IFS) is a type of electrical stimulation. IFS has primarily been investigated as a technique to reduce pain, but has also been proposed to increase function of patients with osteoarthritis and to treat other conditions such as dyspepsia, irritable bowel syndrome, and constipation.
- E. Galvanic Stimulation Devices - High voltage, pulsed stimulation used primarily for local edema reduction through muscle pumping and polarity effect. Edema is comprised of negatively charged plasma proteins. Placing electrodes over the edematous site disperses the negatively charged proteins.
- F. Microcurrent Stimulation Devices (MENS) - Uses a reduced electrical stimulation compared to TENS and acts on naturally occurring electrical impulses to decrease pain.

- G. H-wave Stimulation Devices - H-wave stimulation is a distinct form of electrical stimulation for medical purposes that involve repeated muscle contractions. Hwave electrical stimulation has been evaluated primarily as a pain treatment, but it has also been studied for other indications such as wound healing and improving postsurgical range of motion.
- H. Sympathetic Therapy - Sympathetic therapy describes a type of electrical stimulation of the peripheral nerves that is designed to stimulate the sympathetic nervous system in an effort to "normalize" the autonomic nervous system and alleviate chronic pain. Unlike TENS (transcutaneous electrical nerve stimulation) or interferential electrical stimulation, sympathetic therapy is not designed to treat local pain, but is designed to induce a systemic effect on sympathetically induced pain. (Dynatron STS)
- I. Electrostimulation and Electromagnetic Therapy - Electrostimulation (electrical stimulation) refers to the application of electrical current through electrodes placed directly on the skin. Electromagnetic therapy involves the application of electromagnetic fields, rather than direct electrical current. Both are proposed as treatments for wounds, generally chronic wounds.
- J. Pulsed Electrical Stimulation - Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis (OA) unresponsive to other standard therapies. Electrical stimulation is provided by an electronic device that noninvasively delivers a subsensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils placed over the skin. (BioniCare BIO-1000).
- K. Electrical Stimulation for hyperemesis gravidarum (e.g., Prima Bella) – The PrimBella device is an FDA approved nerve stimulator device worn on the underside of the wrist to reduce nausea and vomiting symptoms during pregnancy.
- L. Neurostimulation for the treatment of migraine pain and prevention of migraine headaches – On March 11, 2014, FDA granted de novo 510(k) approval for marketing to Cefaly® (STX-med), Herstal, Belgium), which is a TENS device for the prophylactic treatment of migraine in patients 18 years of age or older.

**POLICY**

- A. Transcutaneous Electrical Nerve Stimulation Devices (TENS)
1. May be considered **medically necessary** for the treatment of refractory chronic pain (eg, chronic musculoskeletal pain or neuropathic pain)
  2. Are **not medically necessary** for:
    - a. non-musculoskeletal pain, including but not limited to, visceral abdominal pain, and pelvic pain
    - b. acute post op musculoskeletal pain
  3. Are **not medically necessary** using 2 lead, localized stimulation (E0720).
  4. The use of TENS for any other condition is considered **experimental / investigational**.
- B. Form Fitting Conductive Garment  
Is considered **medically necessary** when it meets the indications outlined in Transcutaneous Electrical Nerve Stimulation Devices (TENS) and the patient:
1. Is unable to manage without the garment due to large area or large number of sites  
or
  2. Has skin conditions that preclude the application of conventional electrodes, adhesive tapes and lead wires  
or
  3. Is applying electrical stimulation beneath a cast for disuse atrophy
- C. Neuromuscular Electrical Stimulation Devices (NMES) are denied **experimental / investigational**.
- D. Interferential Therapy is denied **experimental / investigational**. (e.g. Sanexas, RS-4i, Sequential, Stimulator, Medstar&trade 100, EMSI Flex-IT) )
- E. Galvanic Stimulation Devices are denied **experimental / investigational**.
- F. Microcurrent Stimulation Devices (MENS) are denied **experimental / investigational**.
- G. H-wave Stimulation Devices are denied **experimental / investigational**.
- H. Sympathetic Therapy for the treatment of pain is denied **experimental / investigational**.
- I. Electrostimulation and Electromagnetic Therapy for the treatment of chronic wounds is denied **experimental / investigational**.

- J. Pulsed Electrical Stimulation for the treatment of osteoarthritis is denied **experimental / investigational**.
- K. Electrical Stimulation for the treatment of hyperemesis gravidarum is denied **experimental / investigational**.
- L. Neurostimulation for the treatment of migraine pain and prevention of migraine headaches is denied **experimental / investigational**.

## **RATIONALE**

This evidence review has been updated periodically using the MEDLINE database. The most recent literature update was performed through October 12, 2015.

This evidence review was originally based on a 1996 TEC Assessment on transcutaneous electrical nerve stimulation (TENS) for the treatment of chronic and postoperative pain, which concluded that the evidence did not clearly show that the effects of TENS exceeded placebo effects.<sup>2</sup> Over the intervening years, a large number of Cochrane reviews of TENS for a variety of pain conditions have been published, including the topics of osteoarthritis, rheumatoid arthritis, pancreatitis, myofascial trigger points, temporomandibular joint pain, cancer pain, neck pain, acute pain, phantom limb pain, labor pain, and chronic back pain.<sup>3-23</sup> In 2010, the American Academy of Neurology (AAN) published an evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders, including low back pain and diabetic peripheral neuropathy.<sup>24</sup> The evidence on TENS for specific conditions is described next.

### **Chronic Pain**

#### Chronic Pain: Low Back Pain

Cochrane reviews from 2005, updated in 2008, concluded that there is limited and inconsistent evidence for the use of TENS as an isolated treatment for low back pain.<sup>10,11</sup> For the treatment of chronic low back pain, 4 high-quality randomized controlled trials (RCTs) met the selection criteria (585 patients). There was conflicting evidence about whether TENS reduced back pain, and consistent evidence from 2 of the trials (410 patients) indicated that it did not improve back-specific functional status. The review concluded that available evidence did not support the use of TENS in the routine management of chronic low back pain.

In 2010, AAN published an evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders.<sup>24</sup> The evidence on TENS for chronic low back pain of various etiologies (some neurologic) included 2 class I studies (prospective randomized trial with masked outcome assessment in a representative population) and 3 class II studies (randomized trial not meeting class I criteria or a prospective matched group cohort study in a representative population). The class I studies compared TENS with sham TENS for 4 or 6 weeks of treatment. Although both studies were adequately powered to find a 20% or greater difference in pain reduction by visual analog scale (VAS), after correction for multiple comparisons, no significant benefit was found for TENS compared with sham TENS. In 2 of the 3 class II studies, no significant differences were found between TENS and sham TENS. In the third class II study,

benefit was found in 1 of 11 patients treated with conventional TENS, 4 of 11 treated with burst-pattern TENS, and 8 of 11 treated with frequency-modulated TENS. Overall, evidence was conflicting. Because class I studies provide stronger evidence, AAN considered the evidence sufficient to conclude that TENS is ineffective for the treatment of chronic low back pain.

Subsequently, Keskin et al (2012) reported an RCT of TENS for pregnancy-related low back pain.<sup>25</sup> Seventy-nine patients were randomized to 6 TENS sessions over 3 weeks, a home exercise program, acetaminophen, or a no-treatment control. In the control group, pain intensity increased in 57% of participants. Pain decreased in 95% of participants in the exercise group and in all participants in the acetaminophen and TENS groups. VAS improved by a median of 4 points with TENS and by 1 point in the exercise and acetaminophen groups. In the control group, VAS worsened by 1 point. Roland-Morris Disability Questionnaire scores indicated a significantly greater improvement in function in the TENS group (-8.5) compared with the control (+1), exercise (-3), and acetaminophen (-3) groups. This study lacked a sham TENS control.

#### Chronic Pain: Diabetic Peripheral Neuropathy

AAN's 2010 evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders identified 2 class II studies comparing TENS with sham TENS and 1 class III study comparing TENS with high-frequency muscle stimulation for patients with mild diabetic peripheral neuropathy.<sup>24</sup> The studies found a modest reduction in VAS for TENS compared with sham, and a larger proportion of patients experiencing benefit with high-frequency muscle stimulation than with TENS. The authors concluded that, on the basis of these 2 class II studies, TENS is probably effective in reducing pain from diabetic peripheral neuropathy, although presently no studies compare TENS with other treatment options.

A small 2011 RCT found no difference between microcurrent TENS (micro-TENS) compared with sham in 41 patients with diabetic peripheral neuropathy.<sup>26</sup> In this study, current was applied at an intensity of 30 to 40 microamps rather than the usual intensity of several milliamps, and patients were treated for 30 minutes, 3 times per week. After 4 weeks of treatment, 29% of the micro-TENS group and 53% of the sham group showed a response to therapy, defined as a minimum 30% reduction in neuropathic pain score. Median Pain Disability Index was reduced to a similar extent in the TENS group (23%) and the sham group (25%).

#### Chronic Pain: Cancer Pain

For the 2008 Cochrane review on TENS for cancer pain, only 2 RCTs (N=64 participants) met the selection criteria for inclusion in the systematic review.<sup>21</sup> There were no significant differences between TENS and placebo in the included studies. One RCT found no differences between TENS and placebo for pain secondary to breast cancer treatment. The other RCT examined acupuncture-type TENS in palliative care patients but was underpowered. Results of the review were considered inconclusive due to a lack of suitable RCTs. A 2012 update of the Cochrane review identified 1 additional RCT (a feasibility study of 24 patients with cancer bone pain) that met selection criteria.<sup>9</sup> The small sample sizes and differences in patient study populations of the 3 RCTs precluded meta-analysis. Results on TENS for cancer pain remain inconclusive.

#### Chronic Pain: Fibromyalgia

A placebo-controlled crossover RCT from 2013 investigated the effect of a single treatment of TENS in 41 patients with fibromyalgia.<sup>27</sup> Patients were blindly allocated to either no treatment, active TENS treatment, or placebo treatment. Each treatment arm had therapy once weekly for a

3-week period. Patients rated the average pain intensity before and after treatment on a 0-to-10 scale and found that pain with movement was less during active TENS compared with placebo or no TENS ( $p < 0.05$ ). Patients also rated fatigue with movement and found that fatigue decreased with active TENS compared with placebo or no TENS ( $p < 0.05$  and  $p < 0.01$ , respectively). Pressure pain threshold improvement was significantly greater with active TENS (30%,  $p < 0.05$ ) than with placebo (11%) or no TENS (14%).

Another RCT published in 2013 investigated TENS in fibromyalgia. In this trial, 39 patients were randomized into 3 groups: a group with placebo devices at both lumbar and cervical sites, a group with a single active TENS device at the lumbar or cervical site and a placebo device at the second site, and a group with 2 active TENS devices at both lumbar and cervical sites.<sup>28</sup> TENS was administered for 20 minutes at 12-hour intervals for 7 consecutive days. In the dual placebo group, VAS pain scores did not improve compared with baseline. Patients who had a single site of active TENS reported a reduction in pain of 2.5 cm ( $p < 0.05$  vs baseline), and patients in the dual TENS group experienced the greatest reduction in pain of 4.2 cm ( $p < 0.02$  vs baseline). Consumption of medication for pain was also decreased significantly from baseline in the single TENS and dual TENS groups ( $p < 0.05$  and  $p < 0.02$ , respectively). Sleep improvements were reported by 10 patients in the dual TENS group, 8 in the single TENS group, and 4 in the placebo group. Fatigue increased for 3 patients in the placebo group, but decreased in 7 patients in the dual TENS group and 5 patients in the single TENS group. No adverse events were reported.

#### Chronic Pain: Refractory Chronic Pelvic Pain

There is limited literature on the use of TENS for chronic pelvic pain. No RCTs were identified. An observational study of 60 men consecutively treated with TENS for refractory chronic pelvic pain syndrome was published in 2013.<sup>29</sup> TENS was performed at home for 12 weeks with participants keeping a pain diary for the calculation of VAS score. A successful treatment response was defined as a 50% or greater reduction in VAS and absolute VAS of less than 3 at the end of treatment. TENS was successful in 29 (48%) of patients, and treatment response was sustained at a mean follow-up of 44 months (95% confidence interval [CI], 33 to 56). After 12 weeks of treatment, VAS score decreased significantly ( $p < 0.001$ ) from 6.6 to 3.9. Quality of life, assessed by the National Institutes of Health Chronic Prostatitis Symptom Index, improved significantly after 12 weeks of TENS treatment ( $p < 0.001$ ). No adverse events were reported.

#### Chronic Pain: Osteoarthritis of the Knee

A 2009 Cochrane review found that the evidence on TENS for pain relief in patients with osteoarthritis of the knee was inconclusive.<sup>22</sup> Included in the review were 18 small trials in 813 patients; 11 trials used TENS, 4 used interferential current stimulation, 1 trial used both TENS and interferential current stimulation, and 2 trials used pulsed electrostimulation. Methodologic quality and quality of reporting were rated poor. Additionally, there was a high degree of heterogeneity among the trials, and the funnel plot for pain was asymmetrical, suggesting both publication bias and bias from small studies.

Additional randomized trials were published after this systematic review. The largest is a 2014 RCT of 224 participants with osteoarthritis of the knee that assigned patients to 1 of 3 interventions: TENS combined with education and exercise ( $n = 73$ ), sham TENS combined with education and exercise ( $n = 74$ ), or education and exercise alone ( $n = 77$ ).<sup>30</sup> Investigators and participants were blinded to treatment. Participants were treated for 6 weeks and directed to use the TENS device as needed for pain relief. Western Ontario and McMaster Universities Arthritis



Index pain, function, and total scores improved significantly over time from baseline to 24 weeks but did not vary between groups ( $p>0.05$ ). TENS as an adjunct to exercise did not elicit additional benefits.

An RCT with 75 patients examined the effect of a single session of high-frequency TENS, low-frequency TENS, or placebo TENS.<sup>31</sup> Double-blind assessment during the treatment session found a significant increase in pressure pain threshold at the knee for both low- and high-frequency TENS. There was no effect of TENS on cutaneous mechanical pain threshold, heat pain threshold, or heat temporal summation. All 3 groups reported a reduction in pain at rest and during the Timed Up-and-Go (TUG) test, and there were no differences in pain scores between groups. These pain score results suggest a strong placebo component of TENS treatment.

Another small RCT compared intra-articular hyaluronic acid (HA) injections with TENS for the management of knee osteoarthritis in 50 participants.<sup>32</sup> Twenty-seven patients were randomized to HA and received 1 intra-articular injection weekly for 5 weeks. Twenty-three patients in the TENS group received 20-minute sessions of TENS 3 times weekly for 4 weeks. The TENS group exhibited a modest but significantly greater improvement ( $p=0.03$ ) than the HA group on VAS pain score (mean [SD] final score, 4.17 [1.98] vs 5.31 [1.78], respectively) at 2 weeks, but there was no difference between groups at 2 or 3 months posttreatment. The TENS group also had a greater improvement on the Lequesne Index at 2-week follow-up compared with the HA group (mean [SD] final score, 7.78 [2.08] vs 9.85 [3.54], respectively;  $p=0.01$ ) and at 3-month follow-up (mean [SD] final score, 7.07 [2.85] vs 9.24 [4.04], respectively;  $p=0.03$ ). Both treatment groups had significant improvements from baseline to 3 months on scores in walking time, patient global assessment, and disability in activities of daily life.

#### Chronic Pain: Rheumatoid Arthritis

Cochrane reviews from 2002 and 2003 concluded that results in patients with rheumatoid arthritis were conflicting.<sup>4,5</sup>

#### Chronic Pain: Multiple Sclerosis

Sawant et al reported a meta-analysis of 4 RCTs of TENS for the management of central pain in multiple sclerosis.<sup>33</sup> Two studies had a sample size of 10; the other 2 studies had sample sizes of 59 and 60. One study examined the effect of TENS on upper-extremity pain and the other 3 studied the effect of TENS on low back pain. The exact electrode placement could not be identified. Effect sizes extracted from the 4 studies showed a medium sized effect of TENS (Hedges'  $g=0.35$ ,  $p=0.009$ ). The overall level of evidence was considered to be GRADE 2.

#### Chronic Pain: Phantom Limb Pain

A 2015 Cochrane review found no RCTs on TENS for phantom limb pain or stump pain after amputation.<sup>34</sup> The authors concluded that the published literature on TENS for phantom limb pain in adults lacks the methodologic rigor and robust reporting needed to confidently assess its effectiveness and that RCT evidence is required.

#### Chronic Pain: Neck Pain

A 2013 report by the Cochrane Collaboration reviewed the evidence on TENS for the treatment of chronic neck pain.<sup>13</sup> Four studies (2 with high risk of bias, 2 with low risk of bias) compared TENS versus placebo for immediate pain relief. Three studies with a high risk of bias also compared TENS with electrical muscle stimulation, ultrasound, or manual therapy for the treatment of

chronic neck pain. The treatment schedules and differing outcomes precluded pooling of results, and group sizes were very small (7-43 participants) with varied results for TENS therapy. Overall, the quality of this evidence is very low for TENS versus all comparators for the treatment of chronic neck pain.

#### Chronic Pain: Pain After Stroke

Evidence on the efficacy of TENS for shoulder pain after stroke was considered inconclusive in a 2000 Cochrane review.<sup>19</sup>

#### Chronic Pain: Pain After Spinal Cord Injury

A 2014 Cochrane review on nonpharmacologic interventions for chronic pain in individuals with spinal cord injury identified 1 RCT on TENS.<sup>35</sup> This study had a high risk of bias, and no conclusion could be drawn on the effectiveness of TENS compared with sham for reducing chronic pain in this population.

#### Chronic Pain: Headache

A 2004 Cochrane review assessed noninvasive physical treatments for chronic/recurrent headache.<sup>3</sup> Twenty-two studies with a total of 2628 patients (age range, 12-78 years) met inclusion criteria. The review included 5 types of headache and various noninvasive treatments including spinal manipulation, electromagnetic fields, and a combination of TENS and electrical neurotransmitter modulation. Combination TENS and electrical neurotransmitter modulation had weak evidence of effectiveness for migraine headache. Both combination treatment and TENS alone had weak evidence of effectiveness for the prophylactic treatment of chronic tension-type headache. The authors concluded that, although these treatments appear to be associated with little risk of serious adverse effects, clinical effectiveness and cost-effectiveness of noninvasive physical treatments require further research using scientifically rigorous methods.

The Cefaly device (Cefaly; STX-Med, Herstal, Belgium) is a TENS headband device intended for the prophylactic treatment of migraine in patients 18 years of age or older.<sup>1</sup> Clinical information on Cefaly was supplied by 2 studies, the Prevention of Migraine using the STS Cefaly (PREMICE) trial,<sup>36</sup> and a European postmarketing surveillance study.<sup>37</sup> PREMICE was a double-blind, sham-controlled RCT conducted at 5 tertiary care headache clinics in Belgium. Sixty-seven patients were randomized to active (n=34) or sham (n=33) neurostimulation for 3 months, and 59 (88%) completed the trial on protocol. No serious adverse events occurred, although 1 patient discontinued the trial because of a reported device-caused headache. After a 1-month run-in period, patients were instructed to use the device daily for 3 months. Adherence was recorded by the TENS device. Ninety stimulation sessions were expected, but on average, 56 sessions were completed by the active group, and 49 were completed by the sham group. Primary outcome measures were changes in the number of migraine days and the percent of responders. The authors presented both intention-to-treat (ITT) and per-protocol analyses, but only the ITT will be discussed. The reduction in the number of migraine days (run-in vs 3-month) was 2.06 (95% CI, -0.54 to -3.58) for the TENS group versus 0.32 (-0.63 to +1.27) for the sham group; this difference was not statistically significant (p=0.054). The proportion of responders ( $\geq 50\%$  reduction in the number of migraine days/month) was 38% (95% CI, 22% to 55%) in the TENS group versus 12% (95% CI, 1% to 23%) in the sham group (p=0.014). The number of migraine attacks from the run-in period to the 3-month evaluation was significantly lower for the active TENS group (decrease of 0.82 in the TENS group vs 0.15 in the sham group, p=0.044). Number of headache days also was lower in the TENS group than in the sham group (decrease of 2.5 vs

0.2,  $p=0.041$ ). Patients in the active TENS group reported a 36.6% reduction in the number of acute antimigraine drugs taken compared with a 0.5% reduction in the sham group ( $p=0.008$ ). Severity of migraine days did not differ significantly between groups.

Participants rated their satisfaction with treatment more highly in the active group (70.6%) than in the sham group (39%). During postmarketing surveillance, 53% (1226/2313) of participants were satisfied with the device and willing to continue using it. Ninety-nine participants (4%) reported a complaint with the device, although none was a serious adverse event. The most commonly reported adverse events included: insomnia in 4 participants (0.2%), reversible forehead skin irritation in 5 participants (0.2%), headache after a TENS session in 12 participants (0.5%), sleepiness during a Cefaly session (0.5%), and a dislike of how the device felt, leading to discontinuation in 29 participants (1.3%).

#### Chronic Pain: Mixed Chronic Pain Conditions

A 2008 Cochrane review updated the evidence on the use of TENS for the treatment of various chronic pain conditions, including rheumatoid arthritis with wrist pain, temporomandibular joint dysfunction, multiple sclerosis with back pain, osteoarthritis with knee pain, neuropathy, pancreatitis, and myofascial trigger points; it included 25 RCTs (1281 patients).<sup>7,17</sup> Due to heterogeneity, meta-analysis was not possible; slightly more than half of the studies found a positive analgesic outcome in favor of active TENS treatments. The authors concluded that the 6 studies added since the 2001 review did not provide sufficient additional information to change the conclusions, ie, the published literature still lacked the methodologic rigor needed to make confident assessments of the role of TENS in chronic pain management.

An industry-sponsored meta-analysis by Johnson and Martinson (2007) included 38 randomized controlled comparisons (1227 patients from 29 publications) of TENS or percutaneous electrical nerve stimulation (PENS) for chronic musculoskeletal pain, using any stimulation parameters on any location (eg, back, neck, hip, knee).<sup>38</sup> Data were converted to percentage improvement in VAS scores, then transformed into standardized differences (a continuous measure that adjusts for variability in different outcome measures). Based on the combined standardized difference, the authors concluded that TENS provided “nearly 3 times” the pain relief provided by placebo. A number of sources of bias in the analysis seriously limited interpretation of the results. First, statistical heterogeneity of the individual studies ( $I^2=82\%$ ) raises questions about the appropriateness of combining these studies in a meta-analysis (see previous discussion on the decision not to combine studies for the 2000 and 2008 Cochrane reviews on chronic pain). Further limiting interpretation is the transformation of data to standardized effect sizes, which appears to have led to discrepant effect sizes of otherwise similar results. For example, comparison of the untransformed and transformed data showed that while 2 of the included trials (Deyo et al,<sup>39</sup> Machin et al<sup>40</sup>) found similar percentage-point differences in VAS scores between active and control groups (5% and 8%, respectively), standardized effect sizes were not equivalent.

Positive standardized effect sizes from data that were not statistically or clinically significant (eg, 47% vs 42% change from baseline in Deyo et al) also raises concerns about the appropriateness of the data transformation. Inclusion of poor-quality studies is another concern, because several studies with the greatest effect sizes reported dropout rates exceeding 25%. Furthermore, bias for publication of small positive studies may not have been adequately addressed, because the “fail-safe N” method used to assess publication bias is problematic. Another major constraint in

interpretation of this meta-analysis is the lack of clarity about whether PENS resulted in a clinically meaningful improvement. For example, there was no discussion of the magnitude of the combined change in VAS scores or of the proportion of patients who achieved clinically meaningful improvements. Examination of the data indicated that the difference was less than 15% between the electrical nerve stimulation and placebo groups (average difference, 4%) for 13 (34%) of the 38 comparisons. The small effect observed in many of these small studies raises further questions about the impact of publication bias on the meta-analysis. Also at issue is the relative contribution of PENS, because meta-regression found PENS to be more effective than TENS. Given the substantial uncertainty regarding the appropriateness of the studies included, how data were transformed, and the clinical significance of the results, results from this meta-analysis are considered inconclusive.

A 2006 randomized, sham-controlled trial (163 patients with diverse pain states) by Oosterhof et al reported that, although no differences in VAS pain scores were observed, more patients were satisfied (ie, willing to continue treatment) after 10 days (10-12 h/d) of TENS (58%) than after use of a sham device (43%).<sup>41</sup> Analysis of the results by type of pain (osteoarthritic, neuropathic, or bone/soft tissue/visceral) in a subsequent report showed no difference in patient satisfaction for the group with osteoarthritis and related disorders (39% vs 31%, n=31, 26, both respectively) or in patients with neuropathic pain (63% vs 48%, n=16, 25, both respectively), greater satisfaction with TENS in the group of patients with bone and soft tissue injury or visceral pain (74% vs 48%, n=34, 31, both respectively).<sup>42</sup> The nearly 50% patient satisfaction rating in the sham control group suggests a strong nonspecific effect with this treatment protocol. Survival analysis over the course of 1 year revealed no significant difference in the percentage of patients satisfied with treatment (willing to continue).<sup>43</sup> At 1-year follow-up, 30% of the TENS group and 23% of the sham TENS group remained satisfied with treatment (not significantly different). For the satisfied patients, there was no significant difference between the TENS and sham groups in the magnitude of improvement (61.7% vs 63.9%), pain intensity (change in VAS, 27.7 vs 29.4), disability (12.4 vs 12.2), or perceived health status (5.2 vs 5.8), all respectively. This study supported a sustained placebo effect.

## **Acute Pain**

### Acute Pain: Injury

One double-blind, randomized, sham-controlled trial found that during emergency transport of 101 patients, TENS reduced posttraumatic hip pain (change in VAS, 89 to 59), whereas the sham-stimulated group remained relatively unchanged (change in VAS, 86 to 79).<sup>44</sup>

### **Acute Pain: Surgical Pain**

The largest RCT on postsurgical TENS was published by Rakel et al in 2014.<sup>45</sup> This double-blind study compared TENS once or twice daily for 6 weeks versus sham TENS versus standard care to reduce pain during rehabilitation in 317 patients who had undergone total knee arthroplasty (TKA). The primary outcome was pain intensity during range of motion and during walking, measured by a 21-point numeric rating scale on postoperative day 1 and week 6. Secondary outcomes were pain intensity at rest, hyperalgesia, and function. ITT analysis showed that patients who used TENS during exercises had less pain compared with standard care in the near postoperative period, but there was no significant difference in subjective pain compared with patients who used sham TENS. There was also no significant difference between the active and

control groups when tested at 6 weeks. This study, which found no benefit of TENS over placebo or sham, had good methodologic quality and a low risk of bias.

Smaller studies with higher risk of bias tend to support the use of TENS. In 1 double-blind RCT of 40 patients undergoing inguinal herniorrhaphy, two 30-minute sessions of TENS at 2 and 4 hours after surgery (vs sham) reduced both analgesic use and pain scores when measured up to 24 hours postsurgery.<sup>46</sup> A patient-blinded study post abdominal surgery (N=55) found that application of TENS for 1 h/d resulted in a significant reduction in pain, particularly at rest, measured both during and immediately after treatment compared with sham TENS.<sup>47</sup> Pulmonary function (vital capacity, cough peak flow) was also significantly better in the active TENS arm. Another assessor-blinded study of TENS in 74 living kidney donors found a modest reduction in pain at rest and during the measurement of pulmonary function 1 day postoperatively.<sup>48</sup> A single-blinded randomized trial with 42 patients assessed the analgesic effect of TENS after laparoscopic cholecystectomy.<sup>49</sup> Pain improved by a median of 2.4 points of 10 after TENS compared with 0.4 points after placebo treatment. The relative risk of nausea and/or emesis was 2.2 times greater for patients in the placebo group.

It is unclear whether the difference in findings between the RCT by Rakel et al and the smaller RCTs is due to increased risk of bias in small studies, or to differences in time since surgery or type of surgery. One can conclude with relative certainty that TENS has no greater effect than placebo on pain measured at least 1 day following TKA. Additional study is needed to determine the effect of TENS in the immediate postoperative period after other types of surgery.

#### Acute Pain: Bone Marrow Sampling

Tucker et al reported a double-blind RCT of TENS administered during bone marrow sampling in 70 patients.<sup>50</sup> There was no significant difference in a numeric pain score between patients who received strong TENS impulses and the control group that received TENS just above the sensory threshold as reported immediately after the procedure (5.6 vs 5.7, respectively). Over 94% of patients in both groups felt they benefited from TENS.

#### Acute Pain: Dysmenorrhea

One 2002 Cochrane review of 9 small, controlled trials found high-frequency TENS to be effective for the treatment of dysmenorrhea.<sup>20</sup>

#### Acute Pain: Labor and Delivery

A 2009 Cochrane review included 19 studies with 1671 women in labor.<sup>8</sup> Overall, there was little difference in pain ratings between TENS and control groups, although women receiving TENS to acupuncture points were less likely to report severe pain (risk ratio, 0.41). The review found limited evidence that TENS reduces pain in labor or has any impact (either positive or negative) on other outcomes for mothers or babies. The authors concluded that, although it is unclear whether TENS reduces pain, women should have the choice of using TENS in labor if they think it will be helpful.

A placebo-controlled, randomized trial of TENS assessed 200 women who gave birth between January 2010 and July 2010.<sup>51</sup> One hundred women who gave birth vaginally were allocated to active TENS or to sham TENS in a 1:1 ratio; this same assignment was performed for 100 women who gave birth by cesarean delivery. TENS was performed once for 30 minutes after childbirth was completed. After vaginal delivery or cesarean delivery but before administration of TENS, the

placebo and active groups did not significantly differ in VAS scores or verbal numeric scale (VNS) scores. However, after active TENS in the cesarean group, there was a significant reduction in VAS score ( $p < 0.001$ ) and VNS score ( $p < 0.001$ ) compared with the placebo group. Similar benefit was observed in the vaginal delivery group with the active treatment showing a significant reduction in VAS ( $p = 0.022$ ) and VNS ( $p = 0.005$ ) scores. The authors also assessed whether TENS reduced the need for additional analgesia. There was no difference between the active TENS and the placebo groups for vaginal delivery ( $p = 0.83$ ), but, in the cesarean arm, the active treatment group had a significant reduction in analgesic need ( $p = 0.006$ ).

#### Acute Pain: Mixed Acute Pain Conditions

A 2015 Cochrane review assessed the efficacy of TENS as a sole treatment for acute pain conditions that included procedural pain (eg, cervical laser treatment, venipuncture, screening flexible sigmoidoscopy) and nonprocedural pain (eg, postpartum uterine contractions, rib fractures).<sup>52</sup> Nineteen RCTs involving 1346 participants at entry were included. Data on pain intensity were pooled for 6 trials, showing a mean difference of -24.62 mm on a 100-mm VAS in favor of TENS, with significant heterogeneity between the trials. Data on the proportion of participants achieving at least 50% reduction in pain was pooled for 4 trials, with a relative risk of 3.91 in favor of TENS over placebo. There was a high risk of bias associated with inadequate sample sizes in the treatment arms and unsuccessful blinding of treatment interventions. The authors concluded that the analysis provided tentative evidence that TENS reduces pain intensity over and above that seen with placebo, but the high risk of bias makes definitive conclusions impossible.

A systematic review and meta-analysis of TENS for acute pain management in the prehospital setting was published in 2014.<sup>53</sup> A literature search identified 4 sham-controlled RCTs of TENS, including 128 patients. On pooled analysis of these studies, TENS was superior to sham, with a clinically significant reduction in pain severity and a 38-mm reduction on VAS (95% CI, 28 to 48;  $p < 0.001$ ). The 4 studies had significant heterogeneity ( $I^2 = 94\%$ ). The difference in final pain score for TENS versus sham was 33 mm (95% CI, 21 to 44;  $p < 0.001$ ). The authors found that TENS significantly reduced anxiety compared with sham treatment, with an overall 26 mm lower score on VAS for TENS (95% CI, 17 to 35;  $p < 0.001$ ). No studies reported adverse events for TENS.

#### Acute Pain: Tennis Elbow

A multicenter RCT of TENS as an adjunct to primary care management for tennis elbow was identified. Thirty-eight general practices in the West Midlands, U.K., recruited 241 adults who had a new or first diagnosis of tennis elbow.<sup>54</sup> Participants were randomized to TENS once a day for 45 minutes over 6 weeks or until resolution of pain plus primary care management (consultation with a general practitioner followed by information and advice on exercise) versus primary care management alone. Both groups saw large ( $>25\%$ ) within-group improvements in pain intensity, with the greatest improvement during the first 6 weeks of treatment. ITT analysis revealed no difference in improvement of pain (-0.33; 95% CI, -0.96 to 0.31;  $p = 0.31$ ) between the 2 groups at 6 weeks, 6 months (-0.20; 95% CI, -0.81 to 0.42;  $p = 0.526$ ), or 12 months (0.45; 95% CI, -0.15 to 1.06;  $p = 0.139$ ). However, adherence to exercise and TENS was very poor, with only 42 (35%) meeting a prior adherence criteria. Per protocol analyses only showed a statistically significant difference in favor of TENS at 12 months ( $p = 0.030$ ).

## Other

### Other: Dementia

Efficacy of TENS for dementia was considered inconclusive in a 2003 Cochrane review.<sup>6</sup>

### Other: Recovery From Stroke

A 2011 systematic review included 15 randomized or quasi-randomized trials (446 patients) on the use of TENS to enhance motor recovery following stroke.<sup>55</sup> Although methodologic quality of the trials was considered generally good, only 4 studies were large RCTs. In most studies (9/15), fewer than 15 subjects received TENS. Stimulation targets for the various studies included nerves, muscles, acupuncture points, and the entire hand or foot. Most studies reported significant effects on at least 1 outcome measure, although effect sizes were generally small and there were insignificant effects for many outcome measures. Meta-analysis could not be performed for most outcomes because of variability between studies and insufficient data. A moderate effect was determined for force production of ankle dorsiflexion (but not plantarflexion) and for the TUG test (but not the 10-meter gait velocity test or the 6-Minute Walk Test). Overall, results from studies of TENS after stroke were inconsistent.

A paired-sample randomized crossover trial of TENS for improving strength, proprioception, and balance was conducted in 29 mobile stroke survivors who had no preexisting mobility limitations.<sup>56</sup> Participants were given a single session of active TENS plus a session of control sham treatment with each session lasting approximately 1 hour. The authors found that all participants were able to tolerate the TENS treatment, although 1 participant did not feel any stimulation even at maximum intensity of active treatment. Participants improved in forward reach with a difference of 4.16 cm ( $p=0.009$ ), velocity with a difference of 0.03 ms ( $p=0.002$ ), plantarflexor strength with a difference of 4.34 N/m, and joint position sense (JPS) plantarflexion with a difference of  $-1.8^\circ$  ( $p=0.029$ ). Differences for JPS dorsiflexion and dorsiflexor strength did not vary significantly between the TENS and control arms.

## Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Unpublished</b>			
NCT01641471 <sup>a</sup>	Prospective Evaluation of Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Relief Following Total Knee Arthroplasty (TKA)	116	Jun 2015 (completed)
NCT01875042	Does Transcutaneous Electrical Nerve Stimulation (TENS) Affect Pain and Function in Patients With Osteoarthritis of the Knee? ETRELKA, a Randomised Controlled Trial	220	Aug 2015 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## Summary of Evidence

The evidence for transcutaneous electrical nerve stimulation (TENS) in individuals who have chronic pain includes numerous randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The

overall strength of the evidence is weak. The best evidence exists for treatment of chronic, intractable pain. Available evidence indicates that TENS can improve chronic intractable pain in some patients, and there is support for its use in clinical guidelines by specialty societies. To best direct TENS toward patients who will benefit, a short-term trial of TENS is appropriate, with continuation only in patients who show an initial improvement. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for TENS in individuals who have acute pain includes RCTs and systematic reviews. Relevant outcomes are symptoms and medication use. Overall, evidence for the use of TENS from high-quality trials remains inconclusive for most indications. A Cochrane review of TENS for acute pain (eg, cervical laser treatment, venipuncture, screening flexible sigmoidoscopy, postpartum uterine contractions, rib fractures) found some evidence that TENS reduces pain intensity over and above that seen with placebo, but the high risk of bias made definitive conclusions impossible. For the treatment of pain after total knee arthroplasty, 1 large RCT found no benefit of TENS compared with sham TENS. For the prevention of migraine headaches, 1 small RCT reported a greater proportion of patients achieving at least 50% reduction in migraines with TENS than with sham placebo, and modest reductions in the number of total headache and migraine days. This manufacturer-sponsored trial needs corroboration before conclusions can be made about the efficacy of TENS for preventing migraine headaches. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Clinical Input Received From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

#### 2011 Input

In response to requests, input was received through 3 physician specialty societies and 5 academic medical centers while this policy was under review in 2011. Clinical input was generally in agreement with a 30-day trial to determine efficacy of TENS for refractory chronic pain. However, the input did not agree that TENS should be considered not medically necessary for chronic low back pain.

#### 2009 Input

In response to requests, input was received through 4 physician specialty societies (5 reviewers) and 3 academic medical centers (4 reviewers) while this policy was under review in 2009. Clinical input was generally in agreement that TENS is investigational for the management of acute pain and for other conditions such as dementia. Clinical input was for the most part in agreement that TENS is a generally accepted treatment modality and can be beneficial for the management of chronic pain in some patients. A trial period, similar to Medicare Coverage guidelines, was recommended by some.



## **Practice Guidelines and Position Statements**

### European Headache Federation

The European Headache Federation (2013), citing concerns about an ineffective sham procedure for TENS in headache methodology studies and the overall limited level of evidence, recommends that there is insufficient evidence for the use of TENS in headache prophylaxis and to abort an acute headache.<sup>57</sup>

### Osteoarthritis Research Society International

Guidelines from the Osteoarthritis Research Society International (2014) recommend that TENS is not appropriate for use in patients with multijoint osteoarthritis and is of uncertain value for the treatment of knee-only osteoarthritis pain.<sup>58</sup>

### National Comprehensive Cancer Network

National Comprehensive Cancer Network clinical practice guidelines on adult cancer pain (v.2.2014) indicate that nonpharmacologic interventions including TENS may be considered in conjunction with pharmacologic interventions as needed (category 2A).<sup>59</sup>

### National Cancer Institute

National Cancer Institute (2014) guidelines on pain state that noninvasive physical and psychosocial modalities can be used concurrently with drugs and other interventions to manage pain during all phases of treatment. Patients with mild-to-moderate pain may benefit from a trial of TENS to see if it is effective in reducing pain. TENS is a low-risk intervention.<sup>60</sup>

### North American Spine Society

The North American Spine Society (2011) clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders discusses the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and TENS in the treatment of cervical radiculopathy from degenerative disorders. A consensus statement recommends that ozone injections, cervical halter traction, and combinations of medications, physical therapy, injections, and traction have been associated with improvements in patient-reported pain in uncontrolled case series. Such modalities may be considered, recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated.<sup>61</sup>

### American Academy of Neurology

In 2010, the Therapeutics and Technology Assessment Subcommittee of American Academy of Neurology (AAN) published an evidence-based review of the efficacy of TENS for the treatment of pain in neurologic disorders.<sup>62</sup> AAN concluded that TENS is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (level A, established evidence from 2 class I studies), and that TENS should be considered for the treatment of painful diabetic neuropathy (level B, probably effective, based on 2 class II studies).

### American Society of Anesthesiologists et al

2010 Practice guidelines from the American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine recommend that TENS should be used as part of a multimodal approach to management for patients with chronic back pain and may be used for other pain conditions (eg, neck and phantom limb pain).<sup>63</sup> ASA's 1997 guidelines on chronic pain management recommended that an office or home trial of TENS should be considered as an

early management option or as an adjunctive therapy because of its low complexity and low risk.<sup>64</sup>

#### National Institute for Health and Clinical Excellence

The U.K.'s National Institute for Health and Clinical Excellence (NICE) 2009 guidance on low back pain states that, despite the long history of use of TENS for back pain, the quality of research studies is poor.<sup>65</sup> These guidelines failed to recommend TENS as a treatment because there is no evidence that it is effective.

#### National Collaborating Centre for Chronic Conditions et al

The U.K.'s National Collaborating Centre for Chronic Conditions and NICE 2008 guidance on osteoarthritis care and management in adults states that:

"[T]here is evidence that TENS is clinically beneficial for pain relief and reduction of stiffness in knee osteoarthritis, especially in the short term. However, this was not shown in a community setting. There is no evidence that efficacy trails off over time, or that periodic use for exacerbations is helpful.... People with osteoarthritis should be encouraged to experiment with intensities and duration of application if the desired relief of symptoms is not initially achieved. This enables patients' control of their symptoms as part of a self-management approach. A further follow-up visit is essential in allowing the health professional to check patients' usage of TENS and problem solve. No adverse events or toxicity have been reported with TENS."<sup>66</sup>

#### National Collaborating Centre for Women's and Children's Health et al

The U.K.'s National Collaborating Centre for Women's and Children's Health and NICE 2008 guidelines on intrapartum care state that there is high-level evidence that TENS is not an effective analgesic in established labor, and there is no high-level evidence on the analgesic effect of TENS in the latent phase of labor.<sup>67</sup> NICE recommends that TENS not be offered to women in established labor.

#### American Congress of Obstetricians and Gynecologists

American Congress of Obstetricians and Gynecologists (ACOG) 2007 guidelines for women's health care state that methods of neurostimulation, such as TENS, acupuncture, and massage, are based on the gate theory of pain control<sup>68</sup>. These treatments can be useful for pain control, particularly when the pain is severe. The guidelines recommend that because different methods of treatment work by different mechanisms (eg, relaxation techniques, TENS, physical therapy, vocational rehabilitation, biofeedback), the use of multiple treatment modalities in synergy should be considered.

The 2004 ACOG guidelines on chronic pelvic pain found that clinical trials evaluating the efficacy of acupuncture, acupressure, and TENS therapies had been performed only for primary dysmenorrhea, not for no menstrual pelvic pain.<sup>69</sup> The guidelines recommend that acupuncture, acupressure, and TENS therapies should be considered to decrease pain of primary dysmenorrhea.

#### American College of Physicians and American Pain Society

The American College of Physicians and American Pain Society published guidelines on therapies for acute and low back pain in 2007.<sup>70</sup> No recommendations for TENS were made; the panel concluded that TENS had not been proved effective for chronic low back pain.

European Federation of Neurological Societies

The European Federation of Neurological Societies (2007) published guidelines on neurostimulation for neuropathic pain.<sup>71</sup> The task force did not make conclusive recommendations, with only approximately 200 patients with different diseases, based on studies using different parameters and comparators, and having variable results. The task force concluded that standard high-frequency TENS is possibly (level C) better than placebo and probably (level B) worse than acupuncture-like or any other kind of electrical stimulation.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

CPT/HCPCS

- A4556 Electrodes (e.g., apnea monitor), per pair
- A4557 Lead wires (e.g., apnea monitor), per pair
- A4558 Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz.
- A4595 Electrical stimulator supplies, 2 leads, per month (e.g., TENS, NMES)
- A4630 Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
- A9900 Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
- E0720 Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
- E0730 Transcutaneous electrical nerve stimulation (TENS) 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)
- E0744 Neuromuscular stimulator for scoliosis
- E0745 Neuromuscular stimulator, electronic shock unit
- E0761 Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
- E0762 Transcutaneous electrical joint stimulation device system, includes all accessories
- E0765 FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
- E0769 Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
- E1399 Durable medical equipment, miscellaneous
- G0281 Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care

G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses
G0329	Electromagnetic therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care
S8130	Interferential current stimulator, 2 channel
S8131	Interferential current stimulator, 4 channel

There is no specific coding for the Cefaly device. It would most likely be reported with the miscellaneous durable medical equipment code E1399.

#### ICD-9 Diagnoses

643.00-	Excessive vomiting in pregnancy code range
643.93	
716.13	Traumatic arthropathy, forearm
719.41	Pain in joint, shoulder region
719.42	Pain in joint, upper arm
719.43	Pain in joint, forearm
719.44	Pain in joint, hand
719.45	Pain in joint, pelvic region and thigh
719.46	Pain in joint, lower leg
719.47	Pain in joint, ankle and foot
722.4	Degeneration of cervical intervertebral disc
722.51	Degeneration of thoracic or thoracolumbar intervertebral disc
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
722.83	Postlaminectomy syndrome, lumbar region
722.93	Other and unspecified disc disorder of lumbar region
723.1	Cervicalgia
723.4	Brachial neuritis or radiculitis nos
724.02	Spinal stenosis of lumbar region
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
727.61	Complete rupture of rotator cuff
729.5	Pain in limb
805.4	Closed fracture of lumbar vertebra without mention of spinal cord injury
839.69	Closed dislocation, other location
927.20	Crushing injury of hand(s)
928.20	Crushing injury of foot
953.0	Injury to cervical nerve root
955.1	Injury to median nerve
955.2	Injury to ulnar nerve
959.09	Injury of face and neck, other and unspecified

ICD-10 Diagnoses

M12.531	Traumatic arthropathy, right wrist
M12.532	Traumatic arthropathy, left wrist
M25.511	Pain in right shoulder
M25.512	Pain in left shoulder
M25.521	Pain in right elbow
M25.522	Pain in left elbow
M25.531	Pain in right wrist
M25.532	Pain in left wrist
M25.541	Pain in joints of right hand
M25.542	Pain in joints of left hand
M25.551	Pain in right hip
M25.552	Pain in left hip
M25.561	Pain in right knee
M25.562	Pain in left knee
M25.571	Pain in right ankle
M25.572	Pain in left ankle
M46.46	Discitis, unspecified, lumbar region
M46.47	Discitis, unspecified, lumbosacral region
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M48.07	Spinal stenosis, lumbosacral region
M50.11	Cervical disc disorder with radiculopathy, occipito-atlanto-axial region
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy
M50.13	Cervical disc disorder with radiculopathy, cervicothoracic region
M50.31	Other cervical disc degeneration, occipito-atlanto-axial region
M50.321	Other cervical disc degeneration at C4-C5 level
M50.322	Other cervical disc degeneration at C5-C6 level
M50.323	Other cervical disc degeneration at C6-C7 level
M50.33	Other cervical disc degeneration, cervicothoracic region
M51.14	Intervertebral disc disorders with radiculopathy, thoracic region
M51.15	Intervertebral disc disorders with radiculopathy, thoracolumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M51.34	Other intervertebral disc degeneration, thoracic region
M51.35	Other intervertebral disc degeneration, thoracolumbar region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region
M51.86	Other intervertebral disc disorders, lumbar region
M51.87	Other intervertebral disc disorders, lumbosacral region
M54.11	Radiculopathy, occipito-atlanto-axial region
M54.12	Radiculopathy, cervical region
M54.13	Radiculopathy, cervicothoracic region
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region

M54.17	Radiculopathy, lumbosacral region
M54.2	Cervicalgia
M54.31	Sciatica, right side
M54.32	Sciatica, left side
M54.41	Lumbago with sciatica, right side
M54.42	Lumbago with sciatica, left side
<u>M54.50</u>	<u>Low back pain, unspecified (Effective 10-01-2021)</u>
<u>M54.51</u>	<u>Vertebrogenic low back pain (Effective 10-01-2021)</u>
<u>M54.59</u>	<u>Other low back pain (Effective 10-01-2021)</u>
M75.121	Complete rotator cuff tear or rupture of right shoulder, not specified as traumatic
M75.122	Complete rotator cuff tear or rupture of left shoulder, not specified as traumatic
M79.601	Pain in right arm
M79.602	Pain in left arm
M79.604	Pain in right leg
M79.605	Pain in left leg
M79.621	Pain in right upper arm
M79.622	Pain in left upper arm
M79.631	Pain in right forearm
M79.632	Pain in left forearm
M79.641	Pain in right hand
M79.642	Pain in left hand
M79.644	Pain in right finger(s)
M79.645	Pain in left finger(s)
M79.651	Pain in right thigh
M79.652	Pain in left thigh
M79.661	Pain in right lower leg
M79.662	Pain in left lower leg
M79.671	Pain in right foot
M79.672	Pain in left foot
M79.674	Pain in right toe(s)
M79.675	Pain in left toe(s)
M96.1	Postlaminectomy syndrome, not elsewhere classified
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal of lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region
O21.0	Mild hyperemesis gravidarum
O21.1	Hyperemesis gravidarum with metabolic disturbance
O21.2	Late vomiting of pregnancy
O21.8	Other vomiting complicating pregnancy

<b>REVISIONS</b>	
04-04-2011	In Description section: <ul style="list-style-type: none"> <li>Removed "Functional Neuromuscular Stimulation (NMES) - Is a method being developed to restore function to patients with damaged or destroyed nerve pathways through use of an orthotic device with microprocessor controlled electrical neuromuscular stimulation."</li> <li>A stand-alone medical policy for this topic was created entitled Functional Neuromuscular Electrical Stimulation for Home Use.</li> </ul>
	In Policy section: <ul style="list-style-type: none"> <li>Removed, "Functional Neuromuscular Stimulation: Is denied experimental / investigational as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations: <ol style="list-style-type: none"> <li>As a technique to provide ambulation in patients with spinal cord injury; or</li> <li>To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke); or</li> <li>To improve ambulation in patients with foot drop caused by nerve damage (e.g., post-stroke or in those with multiple sclerosis)"</li> </ol> </li> <li>A stand-alone medical policy for this topic was created entitled Functional Neuromuscular Electrical Stimulation for Home Use.</li> </ul>
	In Coding section: <ul style="list-style-type: none"> <li>Updated wording for HCPCS codes: E0730</li> <li>Removed CPT code: E0764, E0770</li> </ul>
	Updated References section.
12-31-2013	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> <li>In Item A 2 revised wording from: "Are not medically necessary for non-musculoskeletal pain, including but not limited to headache, visceral abdominal pain, and pelvic pain." to: "Are not medically necessary for: <ol style="list-style-type: none"> <li>non-musculoskeletal pain, including but not limited to, visceral abdominal pain, and pelvic pain.</li> <li>headache".</li> </ol> </li> </ul>
	In Coding section: <ul style="list-style-type: none"> <li>Added HCPCS codes: A9900, S8130, S8131</li> <li>Added ICD-10 Diagnosis codes</li> </ul>
	Added Rationale section.
	In Revision section: <ul style="list-style-type: none"> <li>Removed Revision comments for the following dates: 01-01-2009, 02-11-2009, 03-22-2010, 06-29-2010</li> </ul>
	References updated
11-05-2014	Policy revisions posted to bcbsks.com web site on 10-06-2014; effective 11-05-2014, 30 days after posting.
	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> <li>Added Item L, "<u>Neurostimulation</u> for the treatment of migraine pain and prevention of migraine headaches (e.g., Cefaly® TENS device): Is denied experimental / investigational."</li> </ul>
	In Coding section: <ul style="list-style-type: none"> <li>Added HCPCS code E1399</li> </ul>
	Updated Rationale section.
	Updated References section.
09-05-2016	Published 08-04-2016. Effective 09-05-2016.

<b>REVISIONS</b>	
	In Title section removed "See also: Functional Neuromuscular Electrical Stimulation for Home Use medical policy" as this policy is no longer on bcbsks.com.
	Description section updated
	In Policy section: <ul style="list-style-type: none"> <li>▪ In Item A 1 added "refractory" and "pain (eg, chronic musculoskeletal pain or neuropathic pain)" and removed "intractable or acute post op musculoskeletal pain" to read "May be considered medically necessary for the treatment of refractory chronic pain (eg, chronic musculoskeletal pain or neuropathic pain)"</li> <li>▪ In Item A 2 added "b. acute post op musculoskeletal pain"</li> <li>▪ In Item A 2 removed "headache" as it is referenced in another section of the policy.</li> <li>▪ Added Item A 4 "The use of TENS for any other condition is considered experimental / investigational."</li> <li>▪ Removed from the TENS section "This policy reflects the long standing accepted standard of care despite lack of evidence of effectiveness."</li> <li>▪ In Item C removed "when used in the home setting. Evidence is lacking regarding improved health outcomes."</li> <li>▪ In Item D removed "(such as the RS-4i)" as device is referenced in the description section.</li> <li>▪ In Item H removed "(Dynatron STS)" as device is referenced in the description section.</li> <li>▪ In Item I removed "in the home setting:"</li> <li>▪ In Item J removed "(BioniCare BIO-1000)" as device is referenced in the description section.</li> <li>▪ In Item K removed "(e.g., Prima Bella)" as device is referenced in the description section.</li> <li>▪ In Item L removed "(e.g., Cafaly TENS device)" as device is referenced in the description section.</li> </ul>
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> <li>▪ Added HCPCS Codes: G0281, G0282, G0295, G0329</li> <li>▪ Removed ICD Codes: M79.643, M79.646</li> </ul>
	References updated
10-01-2016	In Coding section: <ul style="list-style-type: none"> <li>▪ ICD-10 Codes Effective 10-01-2016: M25.541, M25.542, M50.121, M50.122, M50.123, M50.321, M50.322, M50.323</li> <li>▪ ICD-10 Codes Termed 09-30-2016: M50.12, M50.32</li> </ul>
10-01-2017	In Coding section: <ul style="list-style-type: none"> <li>▪ Added ICD-10 Codes: M48.61, M48.62</li> <li>▪ Removed ICD-10 Code: M48.06</li> </ul>
02-24-2021	Medical policy was reviewed with no changes made.
10-01-2021	Title Change to Electrical Stimulation Devices for Home and Provider Use
	In Coding section <ul style="list-style-type: none"> <li>• Deleted ICD-10 code M54.5 (Effective 10-01-2021)</li> <li>• Added ICD-10 code M54.50, M54.41, M54.59 (Effective 10-01-2021)</li> </ul>

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