Medical Policy

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Title: Electrical Stimulation Devices for Home and Provider Use

Professional	Institutional
Original Effective Date: July 1, 2006	Original Effective Date: February 11, 2009
Revision Date(s): January 1, 2009; February 11, 2009; March 22, 2010; June 29, 2010; April 4, 2011; December 31, 2013; November 5, 2014; September 5, 2016; October 1, 2016; October 1, 2017; February 24, 2021: October 1, 2021; February 22, 2022	Revision Date(s): April 20, 2010; June 29, 2010; April 4, 2011; December 31, 2013; November 5, 2014; September 5, 2016; October 1, 2016; October 1, 2017; February 24, 2021; October 1, 2021; February 22, 2022
Current Effective Date: September 5, 2016	Current Effective Date: September 5, 2016

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Populations	Interventions	Comparators	Outcomes
Transcutaneous Electrical Stimulation Devices (TENS) and Form Fitting Conductive Garment			
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:	Comparators of interest are: • Pharmacotherapy	Relevant outcomes include: • Symptoms

Populations	Interventions	Comparators	Outcomes
	• Transcutaneous electrical nerve stimulation		• Medication use
Electrostimulation and Electromagnetic Therapy			
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
Interferential Current Stimulation			
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
Electrical Stimulation for the Treatment of Arthritis			
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

Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin. In addition to more traditional settings such as a physician's office or an outpatient clinic, TENS can be self-administered in a patient's home.

OBJECTIVE

The objective of this evidence review is to determine whether the application of transcutaneous electrical nerve stimulation improves the net health outcome in individuals who suffer from a variety of health conditions including chronic and/or acute pain, essential tremor, and attention deficit hyperactivity disorder.

BACKGROUND

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 is similar to TENS but uses microneedles that penetrate the skin instead of surface electrodes. Interferential stimulation uses a modulated waveform for deeper tissue stimulation, and the stimulation is believed to improve blood flow to the affected area.

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 on clinical efficacy; as a result, these cleared devices are considered substantially equivalent to predicate devices marketed in interstate commerce before May 1976, the enactment date of the Medical Device Amendments. The cleared devices are also equivalent to devices that have been reclassified and do not require a premarket approval application. FDA product code: GZJ.

In 2014, the Cefaly® (STX-Med), which is a TENS device, was granted a de novo 510(k) classification by the FDA for the prophylactic treatment of migraine in patients 18 years of age or older.[1] The Cefaly® Acute and Cefaly® Dual devices were cleared by the FDA through the 510(k) process for the acute treatment of migraine in patients in 18 years of age or older and for both the acute treatment and prophylaxis of migraines in adults, respectively, in 2017.[2,3] Other TENS devices cleared by the FDA through the 510(k) process for the prophylactic treatment of migraine in patients include Allive (Nu Eyne Co) and HeadaTerm (EEspress) among others.[4,5] FDA product code: PCC.

In 2018, the FDA reviewed the Cala ONE™ TENS device (Cala Health) via the de novo pathway and granted approval for the device as an aid in the transient relief of hand tremors following stimulation in the affected hand of adults with essential tremor. This prescription device is contraindicated for use in patients with an implanted electrical medical device, those that have suspected or diagnosed epilepsy or other seizure disorder, those who are pregnant, and patients with swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions. In

October 2020, the FDA granted breakthrough device designation to the Cala Trio™ device for the treatment of action tremors in the hands of adults with Parkinson's disease.[6,]

In 2019, the FDA permitted marketing of the first medical device to treat attention deficit hyperactivity disorder (ADHD) - the Monarch® external Trigeminal Nerve Stimulation (eTNS) System by NeuroSigma.[7,] The FDA reviewed the system through the de novo premarket review pathway. This prescription only TENS device is indicated for patients 7 to 12 years of age who are not currently taking prescription ADHD medication. The Monarch eTNS System is intended to be used in the home under the supervision of a caregiver. The device generates a low-level electrical pulse and connects via a wire to a small patch that adheres to a patient's forehead, just above the eyebrow.

POLICY

A. Transcutaneous Electrical Nerve Stimulation Devices (TENS)
   1. May be considered **medically necessary** for the treatment of refractory chronic pain (e.g., 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.**

POLICY GUIDELINES

A. 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.

B. 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.

C. 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.

D. 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.

E. Microcurrent Stimulation Devices (MENS) - Uses a reduced electrical stimulation compared to TENS and acts on naturally occurring electrical impulses to decrease pain.

F. H-wave Stimulation Devices - H-wave stimulation is a distinct form of electrical stimulation for medical purposes that involve repeated muscle contractions. H-wave 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.

G. 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)

H. 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.

I. 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).

J. 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.

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.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through November 10, 2021.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Transcutaneous Electrical Nerve Stimulation for Chronic Pain

A large number of systematic reviews, most conducted by Cochrane, have assessed the use of transcutaneous electrical nerve stimulation (TENS) in the treatment of a variety of pain conditions, 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.[8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,26,27,28,29] In 2010, the American Academy of Neurology (AAN) published an evidence-based review of the efficacy of TENS for the treatment of pain in neurologic disorders, including low back pain and diabetic peripheral neuropathy.[30]

Clinical Context and Therapy Purpose
The purpose of TENS is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with chronic pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions).

The question addressed in this evidence review is: Does the application of TENS improve the net health outcome in individuals who suffer from chronic pain?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who suffer from chronic pain conditions (e.g., musculoskeletal, neuropathic, and mixed pain conditions).

Interventions
The therapy being considered is TENS.

Comparators
The following therapies are currently being used to treat chronic pain: physical therapy and pharmacotherapy.

Outcomes
The general outcomes of interest are reductions in symptoms and medication use, and improvements in functional outcomes and QOL. Given the different types of pain conditions, follow-up will vary, and some cases will be life-long (e.g., fibromyalgia, arthritis).

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

LOW BACK PAIN

Systematic Reviews
Wu et al (2018) conducted a meta-analysis of RCTs comparing the efficacy of TENS with a control and other nerve stimulation therapies for the treatment of chronic back pain.[31] Reviewers

searched 4 databases (PubMed, Cochrane, Google Scholar, ClinicalTrials.gov) and identified 12 RCTs involving 700 patients. Analysis indicated that TENS had efficacy for providing pain relief similar to control treatment (standard mean difference [SMD], -0.20; 95% confidence interval [CI], -0.5 to 0.18; p=.293) and that other types of nerve stimulation therapies were more effective than TENS (SMD, 0.86; 95% CI, 0.15 to 1.57; p=.017).

Dubinsky et al (2010), who conducted an evidence-based review for AAN, evaluated the efficacy of TENS for treating pain in neurologic disorders.[30] 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, the 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.

Cochrane reviews by Khadilkar et al (2005; 2008), concluded that there is limited and inconsistent evidence for the use of TENS as an isolated treatment for low back pain.[16,17]

Randomized Controlled Trials

Leemans et al (2020) evaluated the effects of heat and TENS in 50 patients with chronic low back pain.[32] Patients were randomized to heat plus TENS or no treatment. At 24 hours after the procedure, there was no significant difference between the groups for average pain in the last 24 hours or maximum pain experienced in the last 24 hours. Measurements were repeated at 4 weeks and no significant differences in pain scores were found between groups at that time point either.

Keskin et al (2012) reported on a RCT of TENS for pregnancy-related low back pain.[33] Seventy-nine patients were randomized to 6 TENS sessions over 3 weeks, a home exercise program, acetaminophen, or 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. The VAS score improved by a median of 4 points in the TENS group and by 1 point in the exercise and acetaminophen groups. In the control group, the VAS score worsened by 1 point. Roland-Morris Disability Questionnaire scores indicated significantly greater improvement in function in the TENS group (-8.5) compared with the control (+1), exercise (-3), and acetaminophen (-3) groups. This trial lacked a sham TENS control. In a subsequent RCT by Jamison et al (2019) that also lacked a sham control group and had fewer patients (n=33), compared to treatment-as-usual, use of high-frequency TENS along with a smartphone tracking app resulted in greater reductions in pain intensity.[34]

Retrospective Studies

Chen et al (2018) conducted a study assessing the efficacy of TENS in treating chronic spinal pain. In this study, 72 patients were assigned to a control group or a treatment group.[35,] Both groups received exercise therapy, and the treatment group also received TENS. After 6 weeks of treatment, the TENS group did not show significant differences in VAS scores (p=.08) or assessments of functional improvement (p=.19), or QOL (p=.18) compared with the control group. Limitations included a low dose of TENS, sample size, and a study design without a full range of outcome assessment data available.

Kong and Gozani (2018) conducted a study to assess the effectiveness of fixed-site high-frequency TENS for treating chronic pain.[36,] The retrospective observational cohort study examined changes in chronic pain measures after 60 days of TENS use for 713 device users who uploaded their data to an online database. Analysis found that the most significant reductions were for pain interference with mood (-1.02, p<.000) and pain interference with activity (-0.99, p=.002), but pain intensity (-0.37, p<.001) and pain interference with sleep (-0.31, p=.081) also saw meaningful reductions. Limitations included the study design, lack of control, and inability to quantify users who discontinued use or did not receive follow-up evaluation due to lack of effectiveness.

DIABETIC PERIPHERAL NEUROPATHY

Systematic Reviews

The AAN's 2010 evidence-based review also 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.[30,] The studies found a modest reduction in VAS scores for TENS compared with sham, and a larger proportion of patients experiencing benefit with high-frequency muscle stimulation than with TENS. Reviewers concluded that, on the basis of these 2 class II studies, TENS was likely effective in reducing pain from diabetic peripheral neuropathy; however, no studies compared TENS with other treatment options.

Randomized Controlled Trials

A small RCT by Gossrau et al (2011) found no difference between microcurrent TENS (micro-TENS) compared with sham in 41 patients with diabetic peripheral neuropathy.[37,] In this trial, the 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 (23%) and sham (25%) groups.

CANCER PAIN

Systematic Reviews

For a Cochrane review by Robb et al (2008), which evaluated TENS for cancer pain, only 2 RCTs (N=64 participants) met the selection criteria.[26,] 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. The results of the review were considered inconclusive due to a lack of suitable RCTs. A 2012 update of the Cochrane review identified an additional RCT (a feasibility study of 24 patients with cancer bone pain) that met selection criteria.[15] The small sample sizes and differences in patient study populations across the 3 RCTs precluded meta-analysis. Results on TENS for cancer pain remain inconclusive.

FIBROMYALGIA

Randomized Controlled Trials

A placebo-controlled crossover randomized trial by Dailey et al (2013) investigated the effect of a single treatment of TENS in 41 patients with fibromyalgia.[38] Patients were blindly allocated to 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 less pain with movement during active TENS than with placebo or no TENS ($p<.05$). Patients also rated fatigue with movement and found that fatigue decreased with active TENS compared with placebo or no TENS ($p<.05$ and $p<.01$, respectively). Pressure pain threshold improvement was significantly greater with active TENS (30%, $p<.05$) than with placebo (11%) or no TENS (14%).

Another RCT by Lauretti et al (2013) investigated TENS in fibromyalgia.[39] However, there was no comparison between active treatment and placebo reported; only change from baseline within each group was reported. 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 ($p<.05$ vs. baseline), and patients in the dual TENS group experienced the greatest reduction in pain (4.2 cm; $p<.02$ vs. baseline). Consumption of medication for pain also decreased significantly from baseline in the single TENS ($p<.05$) and dual TENS groups ($p<.02$). Sleep improvements were reported by 10 patients in the dual TENS group, 8 in the single TENS group, and 4 in the placebo. Fatigue increased for 3 patients in the placebo group but decreased in 7 patients in the dual TENS group; moreover, fatigue decreased for 5 patients in the single TENS group. No adverse events were reported.

Jamison et al (2021) evaluated the efficacy and safety of a wearable TENS device in adults with fibromyalgia.[40] In this single-center, parallel-group study, 119 patients were randomly assigned to a wearable TENS device (Quell®; n=62) or a sham device (n=57) for 3 months. The primary outcome measure was the Patient Global Improvement of Change (PGIC), which represents the patient's overall belief about the efficacy of treatment on a 7 point categorical verbal rating scale. Selection of 1 means "no change or condition has gotten worse" to 7 meaning "a great deal better and a considerable improvement that has made all the difference." Overall, no differences were found between active and sham treatment on PGIC scores at 3 months (mean difference: 0.34; 95% CI, -0.37 to 1.04; $p=.351$) in the intention-to-treat population. In the higher pain sensitivity subgroup, the mean PGIC score at 3 months was 4.05 for active treatment versus 2.86 for sham treatment (mean difference: 1.19; 95% CI, 0.24 to 2.13; $p=.014$). After 3 months of active treatment, all secondary efficacy measures (e.g., disease impact and health-related QOL) exhibited significant within-group improvement compared to pre-treatment baseline. A total of 12 (5 active, 7 sham) adverse events were reported. Nine of the events were definitely or possibly related to TENS use but were minor and self-limited. The authors concluded that the study demonstrated modest treatment effects of reduced disease impact, pain, and functional impairment from wearable TENS in patients with fibromyalgia.

REFRACTORY CHRONIC PELVIC PAIN

Observational Data

There is limited literature on the use of TENS for chronic pelvic pain. No RCTs were identified. An observational study by Schneider et al (2013) assessed 60 men consecutively treated with TENS for refractory chronic pelvic pain syndrome.[41] TENS was performed at home for 12 weeks with participants keeping a pain diary to calculate VAS scores. 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%) patients, and treatment response was sustained at a mean follow-up of 44 months (95% CI, 33 to 56 months). After 12 weeks of treatment, VAS scores decreased significantly (p<.001) from 6.6 to 3.9. QOL, assessed by the National Institutes of Health Chronic Prostatitis Symptom Index, improved significantly after 12 weeks of TENS treatment (p<.001). No adverse events were reported.

OSTEOARTHRITIS OF THE KNEE

Systematic Reviews

A Cochrane review by Rutjes et al (2009) found that the evidence on TENS for pain relief in patients with osteoarthritis of the knee was inconclusive.[27] Included in the review were 18 trials assessing 813 patients; 11 trials used TENS, 4 used interferential current stimulation, 1 used both TENS and interferential current stimulation, and 2 used pulsed electrostimulation. Methodologic quality and quality of reporting were rated as 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.

Randomized Controlled Trials

Additional randomized trials were published after the Rutjeset al (2009) systematic review. Cherian et al (2016) compared TENS with the standard of care in the treatment of 70 patients who had knee osteoarthritis; all patients had previously taken part in a prospective 3-month trial of TENS, allowing researchers to collect data on the long-term efficacy of TENS (mean follow-up time, 19 months).[42] The follow-up study evaluated pain (using a VAS) and function (measured by new Knee Society Scale and Lower-Extremity Functional Scale scores) and a number of secondary outcomes, including medication usage, QOL, device use, and conversion to total knee arthroplasty. For all outcomes, reviewers reported a general trend of improvement for the TENS group compared with the standard of care group; however, no statistical analyses were provided for secondary outcomes, and several differences were not significant among primary outcomes. When measured from pretreatment to final follow-up, Knee Society Scale (p=.002) and Lower-Extremity Functional Scale (p<.001) scores were significantly increased for the TENS group. The trial's limitations included its small sample size and possible variance in the amount of medication taken by each patient. Also, the interviews were not conducted in person, meaning that some conclusions about functional improvement were not confirmed by a physical examination.

A RCT by Palmer et al (2014) evaluated 224 participants with osteoarthritis of the knee who were assigned 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).[43] 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>.05). TENS as an adjunct to exercise did not elicit additional benefits.

In another RCT, Vance et al (2012) assessed 75 patients given a single session of high-frequency TENS, low-frequency TENS, or placebo TENS.[44] All 3 groups reported a reduction in pain at rest and during the Timed Up & Go test, and there were no differences in pain scores between groups.

A RCT by Chen et al (2013) compared intra-articular hyaluronic acid injections with TENS for the management of knee osteoarthritis in 50 participants.[45] Twenty-seven patients were randomized to hyaluronic acid 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=.03) than the hyaluronic acid group on VAS pain score (mean final score, 4.17 vs. 5.31, respectively) at 2 weeks, but there was no difference between groups at 2 or 3 months post-treatment. The TENS group also had greater improvement on the Lequesne Index at a 2-week follow-up compared with the hyaluronic acid group (mean final score, 7.78 vs. 9.85, respectively; p=.01) and at 3-month follow-up (mean final score, 7.07 vs. 9.2, respectively; p=.03). Both treatment groups reported significant improvements from baseline to 3 months on scores in walking time, patient global assessment, and disability in activities of daily life.

RHEUMATOID ARTHRITIS

Systematic Reviews

Two Cochrane reviews (2002, 2003) concluded that outcomes for patients with rheumatoid arthritis treated with TENS were conflicting.[10,11]

MULTIPLE SCLEROSIS

Systematic Reviews

Sawant et al (2015) reported a systematic review of 4 RCTs of TENS for the management of central pain in multiple sclerosis.[46] Sample sizes ranged from 10 to 60 patients. 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=.009). The overall level of evidence was considered to be GRADE 2. Similar findings were reported in a subsequent review by Amatya et al (2018).[47]

PHANTOM LIMB PAIN

Systematic Reviews

A Cochrane review by Johnson et al (2015) found no RCTs on TENS for phantom limb or stump pain after amputation.[48] Reviewers concluded that the published literature on TENS for phantom limb pain in adults lacked the methodologic rigor and robust reporting needed to assess its effectiveness confidently and that RCT evidence is required.

NECK PAIN

Systematic Reviews
A Cochrane review reported by Martimbianco et al (2019) assessed the evidence of TENS for the treatment of chronic neck pain.[19,] Seven RCTs (N=651) comparing TENS alone or in combination with other treatments versus active or inactive treatments were included. Due to heterogeneity in interventions and outcomes, the results were not pooled for a meta-analysis. There was very low-certainty evidence from 2 trials about the effects of conventional TENS versus sham TENS at short-term (up to 3 months after treatment) follow-up. There was no statistically significant difference in outcomes between groups for pain, as assessed by the VAS, (MD -0.10; 95% CI, -0.97 to 0.77) and the percentage of participants presenting improvement of pain (RR 1.57; 95% CI, 0.84 to 2.92). The authors concluded that there is insufficient evidence regarding the use of TENS in patients with chronic neck pain.

Randomized Controlled Trials
Diaz-Pulido et al (2021) compared the effects of manual therapy versus TENS on cervical active mobility and muscle endurance in 90 adults diagnosed with subacute and chronic mechanical neck disorders.[49,] TENS (n=43) and manual therapy (n=47) interventions each consisted of 10 sessions, provided by primary care physical therapists for 30 minutes on alternate days. Outcome measures included active range of motion and endurance of the neck muscles; evaluated pre- and post-intervention and at 6 month follow-up. Of the 90 participants, 72 completed all interventions. Results revealed that manual therapy yielded a significant improvement in active mobility and endurance at post-intervention. At 6 month follow-up, the differences were only significant in endurance and in sagittal plane active mobility. No significant improvement was noted in the TENS group.

PAIN AFTER STROKE

Systematic Reviews
Evidence on the efficacy of TENS for shoulder pain after stroke was considered inconclusive in a Cochrane review by Price et al (2000).[24,]

PAIN AFTER SPINAL CORD INJURY

Systematic Reviews
A Cochrane review by Boldt et al (2014) evaluating nonpharmacologic interventions for chronic pain in individuals with spinal cord injury identified a RCT on TENS.[50,] This trial 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.

HEADACHE

Systematic Reviews
A Cochrane review by Bronfort et al (2004) assessed noninvasive physical treatments for chronic or recurrent headache.[9,] Twenty-two studies with a total of 2628 patients (age range, 12 to 78 years) met inclusion criteria. Reviewers 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 headaches. Both combination treatment and TENS alone had weak evidence of effectiveness for the prophylactic treatment of

chronic tension-type headache. Reviewers concluded that, although these treatments appeared to be associated with little risk of serious adverse events, the clinical effectiveness of noninvasive physical treatments would require further research using scientifically rigorous methods.

Randomized Controlled Trials

The Cefaly device is a TENS headband device intended for the prophylactic treatment of migraine in patients 18 years of age or older.[1] Clinical information on Cefaly was supplied by 2 studies: the Prevention of Migraine using the STS Cefaly (PREMICE) trial (2013)[51]; and a European post marketing surveillance study (2013).[52] PREMICE was a double-blind, sham-controlled, randomized trial 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 trialists presented both intention-to-treat and per-protocol analyses, but BCBSA only assesses the intention-to-treat analysis. 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 and 0.32 (-0.63 to +1.27) for the sham group; this difference was not statistically significant (p=.054). The proportion of responders (≥50% reduction in the number of migraine days/month) was 38% (95% CI, 22% to 55%) in the TENS group and 12% (95% CI, 1% to 23%) in the sham group (p=.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=.044). Moreover, the number of headache days was lower in the TENS group than in the sham group (decrease of 2.5 vs. 0.2, p=.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=.008). The 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 post marketing surveillance, 53% (1226/2313) of participants were satisfied with the device and willing to continue using it. Ninety-nine (4%) participants reported a complaint with the device, but none was a serious adverse event. The most commonly reported adverse events included: insomnia in 4 (0.2%) participants, reversible forehead skin irritation in 5 (0.2%) participants, headache after a TENS session in 12 (0.5%) participants, sleepiness during a Cefaly session (0.5%), and a dislike of how the device felt, leading to discontinuation in 29 (1.3%) participants.

FACIAL MYALGIA

Randomized Controlled Trials

A RCT by De Giorgi et al (2017) evaluated the efficacy of TENS in treating subjective and objective pain in 49 women diagnosed with chronic facial myalgia; 34 patients received TENS treatment daily for 10 weeks and were evaluated for pain up to 25 weeks, and 15 patients received no treatment and were evaluated for pain up to 10 weeks.[53] TENS treatment consisted of daily 60-minute sessions at 50 Hz, and VAS scores were taken for average and maximum pain intensity in the previous 30 days, as well as the level of pain at an examination. The other primary outcome was the assessment of pain at muscular palpation sites, measured by the Pericranial Muscle Tenderness Score and Cervical Muscle Tenderness Score. For this outcome and that of VAS (mean and maximum measurements), patients in the TENS group had significantly lower pain levels than those for the control group at 10 weeks ($p<.05$). Within the TENS group, the trialists found that VAS scores tended to decrease during the trial, as did Pericranial Muscle Tenderness and Cervical Muscle Tenderness scores ($p<.05$). These differences were significant except for the period between 15 and 25 weeks. Secondary outcomes included mandibular movement and range of motion, and the TENS group showed no significant improvement over the control group for either outcome. Although a limitation of the trial was that observation of control patients ended at 10 weeks, these results confirmed the results of several similar studies of TENS in treating musculoskeletal pain. The trialists concluded that TENS is an effective treatment for chronic facial myalgia, although studies with more participants are needed.

TEMPOROMANDIBULAR DISORDER

Randomized Controlled Trials

A randomized placebo-controlled trial by Ferreira et al (2017) evaluated TENS in the treatment of individuals with temporomandibular disorder; 40 patients (30 female, 10 male) were randomized into 2 groups (placebo or active TENS).[54] The trial used both high- and low-frequency TENS, allotting to the active TENS patients 25 minutes of 4 Hz followed by 25 minutes of 100 Hz; measuring pain intensity and pressure pain threshold immediately after treatment and again 48 hours later. When compared with baseline values, pain intensity was reduced for patients in the active TENS group, and pressure pain threshold was significantly increased ($p<.05$). For those in the placebo group, there were no significant improvements for either primary outcome. Limitations of the trial included the short duration of the assessment, and the absence of control groups either receiving no treatment or evaluating the same treatment in patients without the temporomandibular disorder.

MYOFASCIAL TRIGGER POINTS

Systematic Reviews

A systematic review by Ahmed et al (2019) evaluated the effects of various electric stimulation techniques in individuals with myofascial trigger points, including 13 RCTs of TENS compared with sham TENS. High-frequency TENS (>50 Hz) was used in the majority of RCTs. Unclear allocation concealment and blinding were the most common study limitations. Meta-analysis of post-treatment pain intensity scores found that TENs did not significantly reduce pain (SMD, -0.16; 95% CI, 0.39 to 0.07).[55]

Randomized Controlled Trials

Effects of TENS combined with ultrasound were more positive in a RCT by Takla et al (2019) of 70 participants with acute mechanical neck pain and at least 2 active myofascial trigger points. Participants were randomized to 3 sessions per week for 4 consecutive weeks of low-frequency, high-intensity burst TENS combined with ultrasound, medium-frequency, low-intensity amplitude modulated frequency TENS combined with ultrasound or sham combined therapy. Pressure pain threshold and active cervical lateral flexion range of motion were improved in both combined therapy groups - more so in the high-intensity burst TENS combined with ultrasound- but not in the sham group.[56,]

MIXED CHRONIC PAIN CONDITIONS

Systematic Reviews

An overview of a Cochrane review by Gibson et al (2019) evaluated the evidence from 8 Cochrane reviews consisting of 51 RCTs that compared TENS versus sham or usual care/no treatment/waiting list control in 2895 participants with various chronic pain conditions. As with previous reviews, due to the serious methodological limitations described below, authors were unable to draw conclusions about the effects of TENS on pain control, disability, health-related QOL, use of pain-relieving medications, global impression of change, or harms.[57,]

A Cochrane review by Nnoaham and Kumbang (2008) 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. The review included 25 RCTs (N=1281 patients).[13,22,] Due to heterogeneity, a meta-analysis was not possible; slightly more than half of the studies found a positive analgesic outcome in favor of active TENS treatments. Reviewers concluded that the 6 studies added since the earlier review by Carroll et al (2001) did not provide sufficient additional information to change the conclusions (i.e., 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 (e.g., back, neck, hip, knee).[58,] 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, reviewers concluded that TENS provided “nearly 3 times” the pain relief provided by the placebo.

A number of sources of bias in the analysis raised uncertainty in the interpretation of results. First, statistical heterogeneity of the individual studies (I^2=82%) raised questions about the appropriateness of combining these studies in a meta-analysis. Further limiting interpretation was 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 [1990],[59,] Machin et al [1988][60,]) found similar percentage-point differences in VAS scores between active (5%) and control (8%) groups, standardized effect sizes were not equivalent. Positive standardized effect sizes from data that were not statistically or clinically significant (e.g., 47% vs. 42% change from baseline in Deyo et al [1990]) also raised concerns about the appropriateness of the data transformation. The inclusion of poor-quality studies is another concern because several studies with the greatest effect sizes reported dropout rates exceeding 25%. Furthermore, a 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 the 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 between the electrical nerve stimulation and placebo groups was less than 15% for 13 (34%) of the 38 comparisons (average difference, 4%). The small effect observed in many of these small studies raised further questions about the impact of publication bias in the meta-analysis. Also at issue was the relative contribution of PENS, because meta-regression found PENS to be more effective than TENS. Given the substantial uncertainty on the appropriateness of the studies included, how data were transformed, and the clinical significance of the results, the results from this meta-analysis are considered inconclusive.

Randomized Controlled Trials

A randomized, sham-controlled trial (163 patients with diverse pain states) by Oosterhof et al (2006) reported that, although no differences in VAS pain scores were observed, more patients were satisfied (i.e., willing to continue treatment) after 10 days (10 to 12 h/d) of TENS (58%) than after use of a sham device (43%).[61,] Analysis of the results by type of pain (osteoarthritis, 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), and 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).[62,] 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 the treatment (willing to continue).[63,] At 1-year follow-up, 30% of the TENS group and 23% of the sham TENS group remained satisfied with the 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.

Section Summary: Transcutaneous Electrical Nerve Stimulation for Chronic Pain

For individuals who have chronic pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions) who receive TENS, the evidence includes numerous RCTs and systematic reviews. The overall strength of the evidence is weak. The best evidence exists for the treatment of chronic, intractable pain. Systematic reviews have found potential pain relief benefits with TENS for diabetic peripheral neuropathy and chronic headaches. For low back pain and myofascial trigger points, available evidence suggests that TENS is ineffective. Available evidence from systematic reviews are inconclusive for cancer pain, osteoarthritis of the knee, rheumatoid arthritis, phantom knee pain, chronic neck pain, pain after stroke, and pain after spinal cord injury. For the prevention of migraine headaches, a small RCT reported a greater proportion of patients achieving at least a 50% reduction in migraines with TENS than with sham placebo. The RCT also reported 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.

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION FOR ACUTE PAIN

Clinical Context and Therapy Purpose

The purpose of TENS is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with acute pain (e.g., surgical, musculoskeletal, labor, and mixed pain conditions).

The question addressed in this evidence review is: Does the application of TENS improve the net health outcome in individuals who suffer from acute pain?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who suffer from acute pain conditions (e.g., surgical, musculoskeletal, labor, and mixed pain conditions).

Interventions
The therapy being considered is TENS.

Comparators
The following therapy is currently being used to treat acute pain: pharmacotherapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, and medication use. Given the different types of pain conditions, follow-up at 2, 4, and 6 weeks is of interest to monitor outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

INJURY

Randomized Controlled Trials
One double-blind, randomized, sham-controlled trial reported by Lang et al (2007) found that during emergency transport of 101 patients, TENS reduced posttraumatic hip pain (change in VAS score, 89 to 59), whereas the sham-stimulated group remained relatively unchanged (change in VAS score, 86 to 79).[64,]

SURGICAL PAIN

Systematic Reviews

Zimpel et al (2020) conducted a systematic review with meta-analysis to investigate the efficacy of various complementary alternative therapies, including TENS, for post-caesarean pain.[29] Ten studies were included that evaluated TENS, with or without analgesia, for pain relief. One study (N=40) evaluated TENS with no treatment and found that it may reduce pain at 1 hour (MD= -2.26; 95% CI, -3.35 to -1.17). TENS plus analgesia, as compared to placebo plus analgesia, may reduce pain at 1 hour (SMD -1.10, 95% CI -1.37 to -0.82 based on 3 studies with 238 women). Both findings were rated as low-certainty evidence by the Cochrane review.
Zhu et al (2017) conducted a systematic review with meta-analysis to investigate the efficacy of TENS on patients experiencing pain after total knee arthroplasty.[65] Two independent investigators searched PubMed, Embase, Web of Sciences, EBSCO, and Cochrane Library databases and identified 6 RCTs that assessed the effect TENS had on VAS scores of 529 patients who had a total knee arthroplasty. A meta-analysis indicated that, compared with a control intervention, TENS significantly reduced VAS scores over a 24-hour period (SMD= -0.47; 95% CI, -0.87 to -0.08; p=.02). The study was limited by the number of RCTs and sample sizes (4 of 6 selected RCTs had <100 patients), as well as differences in TENS intensities, differences in follow-up times, the ethnic diversity of patients, and possible unpublished or missing data.

Randomized Controlled Trials
Rakel et al (2014) published a RCT on postsurgical TENS.[66] This double-blind study compared TENS once or twice daily for 6 weeks with sham TENS and with standard care to reduce pain during rehabilitation in 317 patients who had undergone total knee arthroplasty. The primary outcome was pain intensity during the range of motion and during walking (as 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. Intention-to-treat 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 trial, which found no benefit of TENS over placebo or sham, had good methodologic quality and a low-risk of bias. Similarly, Ramanathan et al (2017) published a prospective RCT of 66 patients having undergone total knee arthroplasty who were assigned to active or placebo TENS. Patients used the device as needed for 2 hours and had follow-up visits 2, 4, and 6 weeks after surgery.[67] For the primary outcome (reduction of opioid intake), no significant difference was observed between active and placebo TENS groups (p=.60). This was also the case for secondary outcomes, which included assessment of pain, function, and clinical outcomes. The trial was limited by a high withdrawal rate (only 66 of 116 patients enrolled completed the trial) and a lack of uniformity in the device settings chosen by patients. The investigators found no significant benefit of TENS treatment following total knee arthroplasty. Parseliunas et al (2020) evaluated TENS use as a component of multimodal pain control after open inguinal hernia surgery in a randomized, double-blind, placebo-controlled trial.[68] Eighty male patients with unilateral inguinal hernia treated by elective surgery were enrolled and randomly allocated to TENS (n=40) or placebo-TENS (n=40) on the first postoperative day. The primary outcome measure was the change in pain intensity after each TENS application, using VAS and an algometer. Results revealed a significant reduction in VAS pain scores in the TENS group following the procedure (p<.001). Absolute and relative pain relief were significantly improved in the TENS group for pain at rest (p<.01), when walking (p<.01), and when standing up from the bed (p<.01). Administration of additional nonopioid analgesics was reduced in the TENS group on the first and second postoperative days (p<.001). No postoperative surgical complications or TENS-related adverse effects were seen.

Smaller studies with a higher risk of bias - often due to lack of a sham TENS group - have tended to support the use of TENS. In a RCT of 48 patients who had undergone abdominal surgery, compared to a control group that did not receive any electrical stimulation, Oztas et al (2019) found significantly lower pain scores and analgesic consumption in patients who underwent TENS.[69] In an assessor-blinded study of TENS in 74 living kidney donors, Galli et al (2015) found a modest reduction in pain at rest and during the measurement of pulmonary function 1 day postoperatively.[70] A patient-blinded study post abdominal surgery (N=55) by Tokuda et al (2014) found that the application of TENS for 1 hour per day resulted in a significant reduction in pain, particularly at rest, measured both during and immediately after treatment compared with sham TENS.[71] Pulmonary function (vital capacity, cough peak flow) was also significantly better in the active TENS arm. In a single-blind, randomized trial with 42 patients, Silva et al (2012) assessed the analgesic effect of TENS after laparoscopic cholecystectomy.[72] Pain improved by a median of 2.4 points 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. In a double-blind RCT of 40 patients undergoing inguinal herniorrhaphy, DeSantana et al (2008) reported that 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.[73] Pulmonary function (vital capacity, cough peak flow) was also significantly better in the active TENS arm. One exception comes from a single-blind RCT by Forogh et al (2017) of 70 male athletes, which found that adding 20 sessions of high-frequency TENS for 35 minutes a day to semi-supervised exercise did not significantly improve VAS scores.[74]

BONE MARROW SAMPLING

Randomized Controlled Trials

Tucker et al (2015) reported on a double-blind RCT of TENS administered during bone marrow sampling in 70 patients.[75] 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.

LOW BACK PAIN

Systematic Reviews

A systematic review by Binny et al (2019) included 3 placebo-controlled studies with 192 women with acute low back pain. Although a low-quality RCT found that TENS in an emergency-care setting provided clinically worthwhile pain relief for moderate to severe acute low back pain, evidence was inconclusive in the other 2 RCTs. Review authors concluded that, overall, the evidence is insufficient to support or refute the use of TENS for acute low back pain.[76]

Koukoulithras et al (2021) reported a systematic review that included 13 RCTs evaluating the effectiveness of non-pharmaceutical interventions upon pregnancy-related low back pain in 2213 patients.[77] TENS and muscle relaxation exercises accompanied by music were found to be the most effective interventions; having a statistically significant impact on lumbar pain. There was high heterogeneity among the studies including sample sizes.

DYSMENORRHEA

Systematic Reviews

Arik et al (2020) conducted a meta-analysis evaluating the effectiveness of TENS for primary dysmenorrhea.[78] Four randomized controlled trials (N=260) that compared TENS to a sham device were included in the analysis. Pain, as measured by VAS scores, was statistically reduced in the TENS group compared to the sham group (SMD, 1.384; 95% CI, 0.505 to 2.262).

HYSTEROSCOPY

Randomized Controlled Trials

Platon et al (2020) reported the pain relief effects in 74 patients who were randomized to TENS or morphine 5 mg in the post-anesthesia care unit (PACU) after hysteroscopy.[79] At PACU discharge, both groups reported a significant reduction in pain, with a decrease of VAS scores from 5.6 to 1.4 in the TENS group and 5.1 to 1.3 in the opioid group. There was no significant differences between groups. Sixteen patients in each group reported a VAS ≥3 after initial treatment and were crossed over to receive the other treatment during the study as defined by the protocol.

Lison et al (2017) published a RCT assessing the effect of TENS on pain in women undergoing hysterectomy without sedation; the trial included 138 women receiving active TENS, placebo TENS, or neither treatment during the procedure.[80] Women in the active TENS group reported significantly lower VAS scores than women in the control or placebo TENS groups reported. This was the case at each stage measured (entry, contact, biopsy [when necessary], and residual). To validate these measurements, the investigators included a second pain scale (Likert scale) and found a significant correlation with the VAS results (p<.001). For secondary endpoints (e.g., procedure duration, vital parameters, vasovagal symptoms), the trialists reported that differences between the groups were not statistically significant. However, patient satisfaction was significantly higher in the active TENS group than in either placebo TENS or control groups (p<.001 and p=.001, respectively). Trial limitations included the failure to account for the use of a flexible hysteroscope, instead of using a rigid hysteroscope; this might have limited the generalizability of its results.

LABOR AND DELIVERY

Systematic Reviews

A Cochrane review by Deussen et al (2020) included 28 studies involving 2749 women experiencing uterine cramping after vaginal delivery.[81] There was a very low-certainty that TENS is better than no TENS for adequate pain relief as reported by 32 women in 1 applicable RCT.

A systematic review and meta-analysis by Thuvarakan et al (2020) evaluating the efficacy of TENS for labor pain included 26 studies with 3348 patients.[82] TENS showed a statistically significant effect in the reduction of pain intensity (pooled RR, 1.52; 95% CI, 1.35 to 1.70). The authors noted that there was high study heterogeneity (I^2=89%) and the majority of included studies were judged to be low quality.

A Cochrane review by Dowswell et al (2009) included 19 studies with 1671 women in labor.[14] 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 (RR, 0.41). Reviewers found limited evidence that TENS reduced pain in labor or had any impact (either positive or negative) on other outcomes for mothers or babies.

Randomized Controlled Trials

A placebo-controlled, randomized trial by Kayman-Kose et al (2014) assessed 200 women who gave birth between January and July 2010.[83,] One hundred women who gave birth vaginally were allocated to active TENS or 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 or cesarean delivery, but before the administration of TENS, the placebo and active groups did not significantly differ in VAS or verbal numeric scale scores. However, after active TENS in the cesarean group, there was a significant reduction in VAS ($p<.001$) and verbal numeric scale ($p<.001$) scores compared with the placebo group. A similar benefit was observed in the vaginal delivery group with the active treatment showing a significant reduction in VAS ($p=.022$) and verbal numeric scale ($p=.005$) scores. The investigators 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 ($p=.83$), but, in the cesarean arm, the active treatment group had a significant reduction in analgesic need ($p=.006$). Results were consistent in a much smaller RCT by Baez Suarez et al (2019) of 10 women in labor with a breech vaginal delivery. In this RCT, only women who received active TENS experienced a clinically significant improvement in VAS scores.[84,]

Njogu et al (2021) assessed the effects of TENS during the first stage of labor in a single-blind RCT involving 326 adult pregnant women anticipating spontaneous vaginal delivery.[85,] Enrolled patients were randomly assigned to TENS (n=161) or routine obstetric care (n=165) at the beginning of active labor until the second labor stage. The primary outcome was labor pain intensity as assessed by VAS immediately after randomization, at 30, 60, and 120 minutes after TENS therapy, and 2 to 24 hours post-delivery. Prior to the TENS intervention, there was no statistically significant difference in mean VAS scores between the groups ($p>.05$). The TENS group had significantly lower mean VAS scores as compared to control at all time points post-intervention and at 2 to 24 hours post-delivery (all $p<.0001$). The TENS group had a significantly shorter duration of the active labor phase as compared to controls ($p<.001$) and the time of the second and third stages of labor were similar between the groups ($p>.05$). The authors concluded that TENS can be used as a non-pharmacologic therapy to reduce labor pain and shorten the active labor phase duration. Limitations cited were lack of a double-blind, sample size, single-center analysis, and inclusion of only a low-risk pregnancy population.

MEDICAL ABORTION

Randomized Controlled Trials

Goldman et al (2021) evaluated whether the use of TENS reduced pain with medical abortion in a randomized, placebo-controlled trial involving 40 patients.[86,] Enrolled women underwent a medical abortion with mifepristone and misoprostol and were randomly assigned to high-frequency TENS (80 Hz; n=20) or a sham device (n=20) to use at home. The primary outcome was a comparison of maximum pain scores within the first 8 hours after misoprostol administration using an 11-point numeric rating scale. Thirty-seven patients had data evaluable for the primary outcome. Median maximum pain scores within 8 hours after misoprostol were 7 and 10 for the high-frequency TENS and sham device, respectively. Patients administered high-frequency TENS experienced a significant reduction in post-treatment pain score as compared to those who were administered the sham device (-2.0 vs. 0; p=.008). No significant differences between the devices were found with regard to additional analgesia use, distribution of maximum pain scores at 24 hours, adverse effects, or measures of acceptability.

MIXED ACUTE PAIN CONDITIONS

Systematic Reviews

A Cochrane review by Johnson et al (2015) assessed the efficacy of TENS as a sole treatment for acute pain conditions that included procedural pain (e.g., cervical laser treatment, venipuncture, screening flexible sigmoidoscopy) and nonprocedural pain (e.g., postpartum uterine contractions, rib fractures).[87] 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 were 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. Reviewers concluded that the analysis provided tentative evidence that TENS reduced pain intensity over and above that seen with placebo, but the high-risk of bias made definitive conclusions impossible.

A systematic review and meta-analysis of TENS for acute pain management in the prehospital setting was published by Simpson et al (2014).[88] A literature search identified 4 sham-controlled, randomized trials of TENS (N=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 score (95% CI, 28 to 48; p<.001). The 4 studies had significant heterogeneity (I^2=94%). The difference between final pain scores for TENS and sham was 33 mm (95% CI, 21 to 44 mm; p<.001). Reviewers 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<.001). No studies reported adverse events for TENS.

Randomized Controlled Trials

Butera et al (2018) conducted a trial to determine the efficacy of using TENS to reduce musculoskeletal pain and improve function after exercise-induced muscle pain.[89] In this RCT, 36 patients were divided into 3 groups and received TENS, placebo TENS, or no treatment as a control. Treatment was administered for 90 minutes at 24, 48, and 72 hours after the onset of muscle soreness. Analysis indicated that active TENS and placebo TENS had no significant effect on pain. Limitations included a small sample size of young, relatively healthy individuals.

MIGRAINE HEADACHE

Randomized Controlled Trials

A single center RCT (N=78) evaluated the use of TENS in patients presenting to an emergency department with a migraine. Patients were randomized to TENS or a sham device, and their pain was assessed after 20 and 120 minutes.[90] The change in VAS (0 to 100 mm) score from 0 to 20 min was −51.13 ± 2.94 for the TENS group, while the mean VAS score in the sham group was similar between baseline and 20 minutes (73 ± 3 vs. 72 ± 2). The change in VAS (0 to 100 mm) score from 0 to 120 min was -65 ± 25 for the TENS group and -9 ± 2 for the sham group (p<.001).

Domingues et al (2021) evaluated the analgesic efficacy of a portable, disposable, and home self-applied TENS device during migraine attacks.[91,] Participants (74 adults) who had been diagnosed with migraine by a specialist were randomized in this double-blind clinical trial to the active intervention (n=42) or a sham (n=32) with monthly follow-up for 3 months. The primary outcome measure was an evaluation of pain intensity following treatment. Subjects in both groups reported reduced pain scores; with significantly lower pain scores in the intervention group as compared to the sham group (p=.004). Patients in the active intervention group also showed a significant improvement in functional disability scores.

TENNIS ELBOW

Randomized Controlled Trials

A multicenter RCT of TENS as an adjunct to primary care management for tennis elbow was reported by Chesterton et al (2013).[92,] Thirty-eight general practices in the United Kingdom recruited 241 adults who had a new or first diagnosis of tennis elbow. 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. Intention-to-treat analysis revealed no difference in improvement of pain (-0.33; 95% CI, -0.96 to 0.31; p=.31) between the 2 groups at 6 weeks, 6 months (-0.20; 95% CI, -0.81 to 0.42; p=.526), or 12 months (0.45; 95% CI, -0.15 to 1.06; p=.139). However, adherence to exercise and TENS was very poor, with only 42 (35%) meeting prior adherence criteria. Per-protocol analyses only showed a statistically significant difference in favor of TENS at 12 months (p=.03).

Section Summary: Transcutaneous Electrical Nerve Stimulation for Acute Pain

The evidence for the use of TENS from high-quality trials remains inconclusive for most indications of acute pain. A Cochrane review of TENS for acute pain (e.g., 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. Systematic reviews have found that TENS may help reduce pain in patients with post-operative pain (post-caesarean and total knee arthroplasty), dysmenorrhea, and pain associated with labor and delivery. For low back pain, systematic reviews have found insufficient evidence to support or refute the use of TENS. Randomized controlled trials have reported mixed results in the efficacy of TENS across various acute pain conditions.

ESSENTIAL TREMOR

Clinical Context and Therapy Purpose

The purpose of TENS is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with essential tremor.

The question addressed in this evidence review is: Does the application of TENS improve the net health outcome in individuals who suffer from essential tremor?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who suffer from essential tremor.

Interventions
The therapy being considered is TENS of the median nerve. Stimulation of the median nerve has been shown to spike activity in the thalamus.

Comparators
The following therapies are currently being used to treat essential tremor: pharmacotherapy.

Outcomes
The general outcomes of interest are reductions in symptoms and medication use, and improvements in functional outcomes and QOL.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Nonrandomized Studies

Isaacson et al (2020) evaluated the repeated home use of an FDA-cleared wrist-worn neuromodulation device in the Prospective Study for Symptomatic Relief of Essential Tremor with Cala Therapy (PROSPECT) trial.[93,] Key characteristics of the trial are summarized in Table 1. For each active treatment session, the device electrically stimulated the median and radial nerves for 40 minutes with an alternating burst pattern tuned to the frequency of each patient's tremor. The pre-specified co-primary endpoints were improvements on the clinician-rated Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) and patient-rated Bain & Findley Activities of Daily Living (BF-ADL) dominant hand scores. Of the 263 enrolled patients, 205 completed the visit 3 follow-up and were included in the primary analysis. Results revealed a significant improvement in TETRAS and BF-ADL from pre- to post-stimulation at each clinic visit ($p<.0001$ for all comparisons). Pre-stimulation tremor levels were improved from Visit 1 to 3 on both TETRAS and BF-ADL ($p<.0001$ for both). Patients rated as "severe" or moderate" improved with both TETRAS (49.3% at baseline to 21% at study exit) and BF-ADL (64.8% at baseline to 23% at study exit) scoring. Tremor power is a calculation of amplitude and frequency. Tremor power decreases with lower amplitude motions and lower frequency motions. Tremor power was also noted to significantly improve with therapy from pre- to post-stimulation ($p<.0001$). No device-related serious adverse events were reported. Non-serious device-related adverse events occurred in 18% of patients (e.g., persistent skin irritation, sore/lesion, discomfort, electrical burns, and minor skin irritation). Conclusions were that the repeated in home use of this neuromodulation device over 3 months was effective and safe for patients with essential tremor.

Limitations identified were the open-label, single-arm design, the lack of consensus for the definition of clinically meaningful improvement in TETRAS or BF-ADL, as well as the exclusion of 58 patients who exited the study early from the pre-specified primary and secondary endpoint analyses.

Table 1. Summary of Key Nonrandomized Trial

Study	Study Type	Country	Participants	Treatment	Follow-Up
Isaacson et al (2020)[93,]	Prospective, multicenter, single-arm, open-label	U.S. - 26 sites	263 patients (≥22 years) diagnosed with essential tremor having at least 1 dominant hand task scoring ≥2 on the clinician-rated TETRAS and ≥3 on the self-rated BF-ADL, and having a total score across all dominant hand tasks ≥6 on TETRAS and ≥8 on BF-ADL	Cala wrist-worn neuromodulation device; patients were instructed to use the device twice daily for 3 months	Three in-clinic visits: Visit 1 (patient screening and enrollment); Visit 2 (1 month follow-up); Visit 3 (3 month follow-up and study completion)

BF-ADL: Bain & Findley Activities of Daily Living; TETRAS: Tremor Research Group Essential Tremor Rating Assessment Scale.

Section Summary: Transcutaneous Electrical Nerve Stimulation for Essential Tremor
The evidence for the use of TENS for essential tremor includes results from a prospective, open-label, post-clearance, single-arm study. Results of this trial suggest that repeated in home non-invasive neuromodulation therapy is effective and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, the lack of consensus for the definition of clinically meaningful improvement in TETRAS or BF-ADL, as well as the exclusion of 58 patients who exited the study early from the pre-specified primary and secondary endpoint analyses. Further studies comparing TENS to pharmacologic therapy for essential tremor are needed.

ATTENTION DEFICIT HYPERACTIVITY DISORDER

Clinical Context and Therapy Purpose
The purpose of TENS is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with attention deficit hyperactivity disorder (ADHD).

The question addressed in this evidence review is: Does the application of TENS improve the net health outcome in individuals who suffer from ADHD?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who suffer from ADHD (7 to 12 years of age) who are not currently taking prescription ADHD medication.

Interventions
The therapy being considered is TENS. Monarch® external Trigeminal Nerve Stimulation (eTNS) System is based on a purported mechanism of action that the trigeminal nerve stimulates brain areas thought to be involved in ADHD. While the exact mechanism of action is not yet known, neuroimaging studies have shown that eTNS increases activity in the brain regions that are known to be important in regulating attention, emotion, and behavior.

Comparators
The following therapies are currently being used to treat ADHD: pharmacotherapy.

Outcomes
The general outcomes of interest are reductions in symptoms and medication use, and improvements in functional outcomes and QOL.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials
McCough et al (2019) assessed the efficacy and safety of TENS in a double-blind, sham-controlled pilot study of pediatric patients with ADHD.[94,] Key characteristics of the trial are summarized in Table 2. The study was a 4-week trial followed by 1 blinded week without intervention. Clinical assessments included weekly clinician-administered ADHD-Rating and Clinical Global Impression (CGI) scales, and quantitative electroencephalography (EEG) at baseline and week 4. The primary outcome measure was the clinician completed ADHD-Rating Scale total score. Results revealed that ADHD-Rating Scale totals showed significant group-by-time interactions, demonstrating a differential treatment effect (F=8.12, df=1/228, p=.005). The CGI-Improvement scale also favored active treatment over sham (p=.003). Quantitative EEG readings were obtained in both groups but there was no participant specific correlations to other outcomes. No serious adverse events were observed in either group and no patient withdrew from the study due to adverse events. Significant increases in weight and pulse were seen with active TENS over the trial period; however, no differences between active and sham TENS with regard to blood pressure were seen. Conclusions were that TENS therapy is efficacious and well-tolerated in pediatric patients with ADHD. Limitations cited were sample size and short duration of treatment and follow-up.

Table 2. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
McGough et al (2019)[94,]	US	1	NR	62 patients (8 to 12 years) with ADHD based on the KSADS and clinical interview with a minimum total of 24 on the clinician-administered parent ADHD-IV Rating Scale, baseline CGI-S ≥4, and full-scale IQ ≥85 Children were medication free for at least 1 month prior to enrollment	TENS device (Monarch eTNS System) administered nightly for 4 weeks (n=32)	Sham TENS device administered nightly for 4 weeks (n=30)

ADHD: attention deficit hyperactivity disorder; CGI-S: Clinical Global Impression-Severity; IQ: intelligence quotient; KDADS: Kiddie Schedule for Affective Disorders and Schizophrenia; NR: not reported; RCT: randomized controlled trial; TENS: transcutaneous electrical nerve stimulation.

Section Summary: Transcutaneous Electrical Nerve Stimulation for Attention Deficit Hyperactivity Disorder

The evidence for the use of TENS for ADHD includes a RCT. Results concluded that TENS is an effective and safe treatment option for pediatric patients with ADHD; however, the study included a small patient sample and was of relatively short duration.

Summary of Evidence

For individuals who have chronic pain (e.g., musculoskeletal, neuropathic, and mixed pain conditions) who receive TENS, the evidence includes numerous RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. The overall strength of the evidence is weak. The best evidence exists for the 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 that the technology results in an improvement in the net health outcome.

For individuals who have acute pain (e.g., surgical, musculoskeletal, labor, and mixed pain conditions) who receive TENS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL, 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 (e.g., 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. Systematic reviews have found that TENS may help reduce pain in patients with post-operative pain (post-caesarean and total knee arthroplasty), dysmenorrhea, and pain associated with labor and delivery. For low back pain, systematic reviews have found insufficient evidence to support or refute the use of TENS. Randomized controlled trials have reported mixed results in the efficacy of TENS across various acute pain conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have essential tremor who receive TENS, the evidence includes a nonrandomized study. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results from the nonrandomized study suggest that TENS therapy is effective and safe for patients with essential tremor. However, the trial was limited by its open-label, single-arm design, lack of defined standards for what constitutes a clinically meaningful improvement in stated endpoints, and exclusion of patients who exited the study early from the pre-specified primary and secondary endpoint analyses. Further studies comparing TENS to standard of care therapy for essential tremor are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have ADHD who receive TENS, the evidence includes a RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the RCT concluded that TENS is an effective and safe treatment option for pediatric patients with ADHD. However, the study included a small patient sample and was of short duration. Further studies comparing TENS to standard of care therapy for ADHD are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input 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 from 3 physician specialty societies and 5 academic medical centers while this policy was under review in 2011. Input was generally in agreement with a 30-day trial to determine the efficacy of transcutaneous electrical nerve stimulation (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 from 4 physician specialty societies (5 reviewers) and 3 academic medical centers (4 reviewers) while this policy was under review in 2009. The input was generally in agreement that TENS is investigational for the management of acute pain and for other conditions such as dementia. The 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

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Osteoarthritis Research Society International

In 2014, the guidelines from the Osteoarthritis Research Society International recommended that TENS was inappropriate for use in patients with multi-joint osteoarthritis; moreover, the guidelines suggested that TENS has an uncertain value for the treatment of knee-only osteoarthritis pain.[95,] Updated guidance (2019) on the non-surgical management of knee, hip, and polyarticular osteoarthritis does not address TENS nor include it in their patient-focused treatment recommendations.[96,]

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on adult cancer pain (v.2.2021) indicate that nonpharmacologic interventions, including TENS, may be considered in conjunction with pharmacologic interventions as needed (category 2A).[97,]

National Cancer Institute

National Cancer Institute's Physician Data Query identifies TENS as a potential other nonpharmacological modality for pain control for post thoracotomy pain syndrome.[98,]

North American Spine Society

In 2020, the North American Spine Society clinical guidelines on the diagnosis and treatment of low back pain provided guidance on the effectiveness of different physical medicine and rehabilitation therapies.[99,] The guideline noted that there is conflicting evidence that TENS results in improvement in pain or function at short- to medium-term follow-up. The work group further recommended that randomized clinical trials with long-term follow-up are needed to evaluate the benefits of TENS compared to exercise/physical therapy or as adjunctive use to usual care for low back pain.

In 2011, the North American Spine Society clinical guidelines on the diagnosis and treatment of cervical radiculopathy from degenerative disorders discussed the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture, and TENS in the treatment of cervical radiculopathy from degenerative disorders.[100,] A consensus statement from the Society recommended 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.

American Academy of Neurology
In 2010, the American Academy of Neurology published an evidence-based review of the efficacy of TENS for the treatment of pain in neurologic disorders.[30,] The Academy did not recommend TENS 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
In 2010, the practice guidelines from the American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine recommended that TENS be used as part of a multimodal approach to management for patients with chronic back pain and may be used for other pain conditions (e.g., neck and phantom limb pain).[101,]

National Institute for Health and Care Excellence
In 2016, the National Institute for Health and Care Excellence (NICE) guidance on low back pain indicated that, despite the long history of use of TENS for back pain, the quality of research studies is poor.[102,] This guidance recommended against TENS as a treatment.

In 2014, the NICE guidance on osteoarthritis care and management in adults indicated that TENS be considered "as an adjunct to core treatments for pain relief."[103,]

In 2017, the NICE guidance on intrapartum care recommended against the use of TENS for "established labour."[104,]

American Congress of Obstetricians and Gynecologists
In 2019 (reaffirmed in 2021), the ACOG guidelines on labor and delivery found that TENS may "help women cope with labor more than directly affect pain scores."[105,]

American College of Physicians
In 2017, the American College of Physicians published guidelines on noninvasive therapies for acute and low back pain.[106,] No recommendations for TENS were made; the College concluded that "evidence was insufficient to determine the effectiveness" of TENS and that there was no long-range data.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04114149	Effective Postoperative Pain Relief After Laparoscopic Cholecystectomy With TENS Treatment for First Line of Treatment Compared to Conventional Treatment With Opioids	166	Mar 2024
Unpublished			
NCT04092088	Effectiveness of Cerebral and Peripheral Electrical Stimulation on Pain and Functional Limitations Associated With Carpal Tunnel Syndrome: A Randomized, Double-blind, Multi-center, Factorial Clinical Trial	180	Oct 2020
NCT04399707	Transcutaneous Electrical Nerve Stimulation for Post-Cesarean Pain Control	180	May 2021
NCT04851938	Evaluation of the Effect of Transcutaneous Electrical Nerve Stimulation Applied in Different Frequencies on Hormone Levels, Birth Pain Perception and Anxiety During Delivery	112	Jun 2021
NCT02642796	Comparison of the Efficacy of 2 Different Transcutaneous Electrical Nerve Stimulation Application Sites in Reducing Postoperative Pain After Hip Fracture Surgery	120	Sep 2021

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

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.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

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

CPT/HCPCS	
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-10 DIAGNOSES	
G89.21-G89.8	Chronic pain, not elsewhere classified, code range,
G89.4	Chronic pain syndrome
G90.50-G90.59	Complex regional pain syndrome I (CRPS I), code range,
M25.50-M25.579	Pain in joint, code range,
M12.531	Traumatic arthropathy, right wrist
M12.532	Traumatic arthropathy, left wrist
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
M54.10- M54.18	Radiculopathy, code range,

ICD-10 DIAGNOSES	
M54.2	Cervicalgia
M54.30-M54.32	Sciatica, code range,
M54.40-M54.42	Lumbago with sciatica, code range,
M54.50	Low back pain, unspecified
M54.51	Vertebrogenic low back pain (Effective 10-01-2021)
M54.59	Other low back pain (Effective 10-01-2021)
M54.6	Pain in thoracic spine
M54.81-M54.89	Other dorsalgia codes
M54.9	Other dorsalgia codes
M79.1	Myalgia
M79.2	Neuralgia and neuritis, unspecified
R52	Neuralgia and neuritis, unspecified
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

ICD-10 DIAGNOSES	
O21.0	Mild hyperemesis gravidarum
O21.1	Hyperemesis gravidarum with metabolic disturbance
O21.2	Late vomiting of pregnancy
O21.8	Other vomiting complicating pregnancy

REVISIONS	
04-04-2011	In Description section: ▪ 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." ▪ A stand-alone medical policy for this topic was created entitled Functional Neuromuscular Electrical Stimulation for Home Use.
	In Policy section: ▪ 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: 1. As a technique to provide ambulation in patients with spinal cord injury; or 2. To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke); or 3. To improve ambulation in patients with foot drop caused by nerve damage (e.g., post-stroke or in those with multiple sclerosis)" ▪ A stand-alone medical policy for this topic was created entitled Functional Neuromuscular Electrical Stimulation for Home Use.
	In Coding section: • Updated wording for HCPCS codes: E0730 • Removed CPT code: E0764, E0770
	Updated References section.
12-31-2013	Updated Description section.
	In Policy section: ▪ 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: a. non-musculoskeletal pain, including but not limited to, visceral abdominal pain, and pelvic pain. b. headache".
	In Coding section: ▪ Added HCPCS codes: A9900, S8130, S8131 ▪ Added ICD-10 Diagnosis codes
	Added Rationale section.
	In Revision section: ▪ Removed Revision comments for the following dates: 01-01-2009, 02-11-2009, 03-22-2010, 06-29-2010
	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:

REVISIONS	
	▪ Added Item L, "Neurostimulation for the treatment of migraine pain and prevention of migraine headaches (e.g., Cefaly® TENS device): Is denied experimental / investigational."
	In Coding section: ▪ Added HCPCS code E1399
	Updated Rationale section.
	Updated References section.
09-05-2016	Published 08-04-2016. Effective 09-05-2016.
	In Title section removed "See also: Functional Neuromuscular Electrical Stimulation for Home Use medical policy" as this policy is no longer on bcbcsks.com.
	Description section updated
	In Policy section: ▪ 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)" ▪ In Item A 2 added "b. acute post op musculoskeletal pain" ▪ In Item A 2 removed "headache" as it is referenced in another section of the policy. ▪ Added Item A 4 "The use of TENS for any other condition is considered experimental / investigational." ▪ Removed from the TENS section "This policy reflects the long standing accepted standard of care despite lack of evidence of effectiveness." ▪ In Item C removed "when used in the home setting. Evidence is lacking regarding improved health outcomes." ▪ In Item D removed "(such as the RS-4i)" as device is referenced in the description section. ▪ In Item H removed "(Dynatron STS)" as device is referenced in the description section. ▪ In Item I removed "in the home setting:" ▪ In Item J removed "(BioniCare BIO-1000)" as device is referenced in the description section. ▪ In Item K removed "(e.g., Prima Bella)" as device is referenced in the description section. ▪ In Item L removed "(e.g., Cafaly TENS device)" as device is referenced in the description section.
	Rationale section updated
	In Coding section: ▪ Added HCPCS Codes: G0281, G0282, G0295, G0329 ▪ Removed ICD Codes: M79.643, M79.646
	References updated
10-01-2016	In Coding section: ▪ ICD-10 Codes Effective 10-01-2016: M25.541, M25.542, M50.121, M50.122, M50.123, M50.321, M50.322, M50.323 ▪ ICD-10 Codes Termed 09-30-2016: M50.12, M50.32
10-01-2017	In Coding section: ▪ Added ICD-10 Codes: M48.61, M48.62 ▪ Removed ICD-10 Code: M48.06
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 • Deleted ICD-10 code M54.5 (Effective 10-01-2021)

REVISIONS	
	• Added ICD-10 code M54.50, M54.41, M54.59 (Effective 10-01-2021)
02-22-2022	Updated Description Section
	Updated Policy Guidelines ▪ Moved product descriptions from under Regulatory Status section to Policy Guidelines Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-9 Codes ▪ Added ICD-10 Codes G89.21-G89.8, G89.4, G90.50-G90.59, M54.81-M54.89, M54.9, M79.1, M79.2, R52
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