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1.01.09	Transcutaneous Electrical N	lerve Stimulation	
Original Policy Date:	April 3, 2009	Effective Date:	February 1, 2020
Section:	1.0 Durable Medical Equipment	Page:	Page 1 of 27

## **Policy Statement**

A trial of transcutaneous electrical nerve stimulation (TENS) of at least 30 days may be considered **medically necessary** to establish efficacy for the management of refractory chronic pain (e.g., chronic musculoskeletal pain or neuropathic pain) that causes significant disruption of function when **both** of the following conditions have been met:

- The pain is unresponsive to at least 3 months of conservative medical therapy
- The trial is monitored by a physician

Continued use of TENS may be considered **medically necessary** for treatment of refractory chronic pain (e.g., chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when **both** of the following conditions have been met:

- Compliance has been demonstrated in the therapeutic trial with the device used on a regular basis (e.g., daily or near daily use) throughout the trial period
- Efficacy has been demonstrated in an initial therapeutic trial (see Policy Guidelines section)

TENS is considered **investigational** for any other condition, including but not limited to the following:

- Management of acute pain (e.g., postoperative or during labor and delivery)
- Prevention of migraine headaches
- Treatment of dementia

Form-fitting conductive garments may be considered **medically necessary** when used in conjunction with a medically necessary transcutaneous electrical nerve stimulation (TENS) device and **one** of the following conditions exists:

- A skin problem prevents the application of conventional electrodes, adhesive tapes, and lead wires
- Area or sites to be stimulated are inaccessible with conventional electrodes, adhesive tapes, or lead wires for the patient
- There is a large area or many sites to be stimulated

## **Policy Guidelines**

For the purposes of these policy guidelines, refractory chronic pain is defined as pain that causes significant disruption of function and has not responded to at least 3 months of conservative therapy, including nonsteroidal anti-inflammatory medications, ice, rest, and/or physical therapy.

Documentation for the trial should include:

- Initial assessment/evaluation of the nature, duration, and perceived intensity of pain
- The types and duration of prior treatments
- Treatment plan including ongoing medications and proposed use of transcutaneous electrical nerve stimulation (TENS) unit, including the frequency and duration of treatment

Clinical summary of the trial to determine efficacy should include **all** of the following:

- Actual use of TENS on a daily basis (frequency and duration of application)
- Ongoing medication requirements for pain relief (if any)
- Other modalities (if any) in use for pain control

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• Perceived intensity of pain with and without TENS (e.g., 2-point or 30% improvement in visual analog scale [VAS])

TENS devices may be delivered through a practitioner and require a prescription or obtained without a prescription. It is possible that prescribed devices provide higher intensity stimulation than units sold directly to the public.

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

## **TENS Supplies**

The following supplies are used in conjunction with a TENS unit and are included in the rental allowance:

- Adhesive removal, skin preparation materials (A4455, A4456)
- Batteries, any (A4630)
- Battery charger, if rechargeable batteries are used
- Conductive paste or gel, if needed (A4558)
- Electrodes, any type (A4556)
- Lead wires (A4557, A4595)
- Tape or other adhesive, if needed (A4364, A4450, A4452)

Note: A 4 lead TENS unit may be used with either 2 leads or 4 leads, depending on the characteristics of the patient pain.

The following supplies are included in the first months allowance for a TENS purchase:

- Batteries (A4630)
- Conductive paste or gel, if needed, (A4558)
- Lead wires (A4557)
- One month's supply of electrodes, any type (A4556)

No separate or additional reimbursement is made for the following devices as they are considered items of convenience and are not covered benefits:

- Adapters (i.e., snap, banana, alligator, tab, button, clip)
- Belt clips
- Carrying pouches
- Covers

## Description

Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin at the site of pain. 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.

## **Related Policies**

- Interferential Current Stimulation
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
- Temporomandibular Joint Disorder

## **Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## **Regulatory Status**

TENS devices consist of an electrical pulse generator, usually battery-operated, connected by wire to two 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<sup>®</sup> (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.<sup>1,</sup> FDA product code: PCC.

## Rationale

## Background

Transcutaneous electrical nerve stimulation (TENS) has been used to treat chronic intractable pain, postsurgical pain, and pain associated with active or posttrauma 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 (see Blue Shield of California Medical Policy: Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy) is similar to TENS but uses microneedles that penetrate the skin instead of surface electrodes. Interferential stimulation (see Blue Shield of California Medical Policy: Interferential Current Stimulation) uses a modulated waveform for deeper tissue stimulation, and the stimulation is believed to improve blood flow to the affected area.

## Literature Review

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, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one 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

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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. RCTs 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 review, most conducted by Cochrane, have assessed the use of 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.<sup>2-23,</sup> 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.<sup>24,</sup> The evidence on TENS for specific conditions is described next.

## **Clinical Context and Test 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 PICOs were used to select literature to inform this review.

## Patients

The relevant populations of interest are individuals who suffer from chronic pain conditions (e.g., musculoskeletal, neuropathic, and mixed pain conditions). Patients with chronic pain are actively managed by physical therapists, neurologists, rheumatologists, oncologists, physiatrists, and primary care physicians in an outpatient setting.

## 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

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## 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.<sup>25,</sup> Reviewers searched 4 databases (MEDLINE, 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% CI, -0.5 to 0.18; p=0.293) and that other types of nerve stimulation therapies were more effective than TENS (SMD=0.86; 95% CI, 0.15 to 1.57; p=0.017). Limitations included the small number of studies, variations in the lengths of interventions and follow-up, and differences in comorbidities of enrolled patients.

Dubinsky et al (2010), who conducted an evidence-based review for AAN, evaluated the efficacy of TENS for treating pain in neurologic disorders.<sup>24,</sup> The evidence on TENS for chronic low back pain of various etiologies (some neurologic) included two class I studies (prospective randomized trial with masked outcome assessment in a representative population) and three 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 four or six 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 two of the three 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.<sup>10,11,</sup> For the treatment of chronic low back pain, 4 high-quality RCTs met the selection criteria (n=585 patients). There was conflicting evidence about whether TENS reduced back pain and consistent evidence from 2 of the trials (n=410 patients) indicating that it did not improve back-specific functional status. Reviewers concluded that available evidence did not support the use of TENS in the routine management of chronic low back pain.

## Randomized Controlled Trials

Keskin et al (2012) reported on an RCT of TENS for pregnancy-related low back pain.<sup>26,</sup> Seventynine patients were randomized to six TENS sessions over three 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 four points in the TENS group and by one point in the exercise and acetaminophen groups. In the control group, the VAS score worsened by one 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.<sup>27,</sup>

## **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.<sup>28,</sup> Both groups received exercise therapy, and the treatment group also received TENS therapy. After 6 weeks of treatment, the TENS group did not show significant differences in VAS scores (p=0.08) or assessments of functional improvement (p=0.19), or QOL (p=0.18) compared with the control

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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 highfrequency TENS for treating chronic pain.<sup>29,</sup> 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<0.000) and pain interference with activity (-0.99, p=0.002), but pain intensity (-0.37, p<0.001) and pain interference with sleep (-0.31, p=0.081) 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.<sup>24,</sup> 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 two 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.<sup>30,</sup> 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 group (23%) and the sham group (25%).

## **Cancer** Pain

For a Cochrane review by Robb et al (2008), which evaluated TENS for cancer pain, only 2 RCTs (total n=64 participants) met the selection criteria.<sup>21,</sup> There were no significant differences between TENS and placebo in the included studies. One RCT found no differences between TENS and placebo for pain secondary to breast cancer treatment. The other RCT examined acupuncture-type TENS in palliative care patients but was underpowered. 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.<sup>9,</sup> The small sample sizes and differences in patient study populations across the three RCTs precluded meta-analysis. Results on TENS for cancer pain remain inconclusive.

## Fibromyalgia

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.<sup>31,</sup> Patients were blindly allocated to no treatment, active TENS treatment, or placebo treatment. Each treatment arm had therapy once weekly for a three-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<0.05). Patients also rated fatigue with movement and found that fatigue decreased with active TENS compared with placebo or no TENS (p<0.05 and p<0.01, respectively). Pressure pain threshold improvement was significantly greater with active TENS (30%, p<0.05) than with placebo (11%) or no TENS (14%).

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Another RCT by Lauretti et al (2013) investigated TENS in fibromyalgia.<sup>32,</sup> In this trial, 39 patients were randomized into 3 groups: a group with placebo devices at both lumbar and cervical sites, a group with a single active TENS device at the lumbar or cervical site and a placebo device at the second site, and a group with 2 active TENS devices at both lumbar and cervical sites. TENS was administered for 20 minutes at 12-hour intervals for 7 consecutive days. In the dual placebo group, VAS pain scores did not improve compared with baseline. Patients who had a single site of active TENS reported a reduction in pain of 2.5 cm (p<0.05 vs baseline), and patients in the dual TENS group experienced the greatest reduction in pain (4.2 cm; p<0.02 vs baseline). Consumption of medication for pain also decreased significantly from baseline in the single TENS (p<0.05) and dual TENS groups (p<0.02). Sleep improvements were reported by ten patients in the dual TENS group, eight in the single TENS group, and four in the placebo group. Fatigue increased for three patients in the placebo group but decreased in seven patients in the dual TENS group; moreover, fatigue decreased for five patients in the single TENS group. No adverse events were reported.

## Refractory Chronic Pelvic Pain

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.<sup>33,</sup> 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%) of patients, and treatment response was sustained at a mean follow-up of 44 months (95% confidence interval [CI], 33 to 56 months). After 12 weeks of treatment, VAS scores decreased significantly (p<0.001) 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<0.001). 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.<sup>22,</sup> Included in the review were 18 small 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 Rutieset al (2009) systematic review. Cherian et al (2016) compared TENS with the standard of care in the treatment for 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).<sup>34,</sup> 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=0.002) and Lower-Extremity Functional Scale (p<0.001) 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 large 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).<sup>35,</sup> Investigators and participants were blinded to treatment. Participants were treated for six weeks and directed to use the TENS device as needed for pain relief. Western Ontario and McMaster Universities Arthritis Index pain, function, and total scores improved significantly over time from baseline to 24 weeks but did not vary between groups (p>0.05). TENS as an adjunct to exercise did not elicit additional benefits.

In another RCT, Vance et al (2012) assessed 75 patients given a single session of high-frequency TENS, low-frequency TENS, or placebo TENS.<sup>36,</sup> Double-blind assessment during the treatment session found a significant increase in pressure pain threshold at the knee for both low- and high-frequency TENS. There was no effect of TENS on cutaneous mechanical pain threshold, heat pain threshold, or heat temporal summation. All three 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. These pain score results suggested a strong placebo component of TENS treatment.

A small RCT by Chen et al (2013) compared intra-articular hyaluronic acid injections with TENS for the management of knee osteoarthritis in 50 participants.<sup>37,</sup> Twenty-seven patients were randomized to hyaluronic acid and received one intra-articular injection weekly for five weeks. Twenty-three patients in the TENS group received 20-minute sessions of TENS 3 times weekly for 4 weeks. The TENS group exhibited a modest but significantly greater improvement (p=0.03) than the 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 posttreatment. 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=0.01) and at 3-month follow-up (mean final score, 7.07 vs 9.2, respectively; p=0.03). Both treatment groups reported significant improvements from baseline to three months on scores in walking time, patient global assessment, and disability in activities of daily life.

## **Rheumatoid Arthritis**

Two Cochrane reviews (2002, 2003) concluded that outcomes for patients with rheumatoid arthritis treated with TENS were conflicting.<sup>4,5,</sup>

## **Multiple Sclerosis**

Sawant et al (2015) reported a systematic review of 4 RCTs of TENS for the management of central pain in multiple sclerosis.<sup>38,</sup> Sample sizes ranged from 10 to 60 patients. One study examined the effect of TENS on upper-extremity pain, and the other three studied the effect of TENS on low back pain. The exact electrode placement could not be identified. Effect sizes, extracted from the 4 studies, showed a medium-sized effect of TENS (Hedges' g=0.35, p=0.009). The overall level of evidence was considered to be GRADE 2. Similar findings were reported in a subsequent review by Amatya et al (2018).<sup>39,</sup>

## **Phantom Limb Pain**

A Cochrane review by Johnson et al (2015) found no RCTs on TENS for phantom limb or stump pain after amputation.<sup>40,</sup> 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

A Cochrane review reported by Kroeling et al (2013) assessed the evidence on TENS for the treatment of chronic neck pain.<sup>13,</sup> Four studies (two with a high-risk of bias, two with a low-risk of bias) compared TENS with placebo for immediate pain relief. Three studies with a high-risk of bias also compared TENS with electrical muscle stimulation, ultrasound, or manual therapy for the treatment of chronic neck pain. The treatment schedules and differing outcomes precluded pooling of results, and group sizes were very small (7-43 participants) with varied results for TENS

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therapy. Overall, the quality of this evidence is very low for TENS vs all comparators for the treatment of chronic neck pain. A subsequent RCT by Yesil et al (2018) found that neither TENS nor interferential current increased the 12-week effectiveness of neck stabilization exercises on pain, disability, mood and QOL in 81 patients with chronic neck pain.<sup>41,</sup>

## Pain After Stroke

Evidence on the efficacy of TENS for shoulder pain after stroke was considered inconclusive in a Cochrane review by Price et al (2000).<sup>19,</sup>

## Pain After Spinal Cord Injury

A Cochrane review by Boldt et al (2014)<sup>42,</sup> evaluated nonpharmacologic interventions for chronic pain in individuals with spinal cord injury identified an RCT on TENS. This trial had a highrisk 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.<sup>3,</sup> Twenty-two studies with a total of 2628 patients (age range, 12-78 years) met inclusion criteria. Reviewers included five 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. Combination treatment and TENS alone 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.<sup>1,</sup> Clinical information on Cefaly was supplied by 2 studies: the Prevention of Migraine using the STS Cefaly (PREMICE) trial (2013)<sup>43,</sup>; and a European postmarketing surveillance study (2013).<sup>44,</sup> PREMICE was a double-blind, sham-controlled randomized trial conducted at five 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 one patient discontinued the trial because of a reported device-caused headache. After a one-month run-in period, patients were instructed to use the device daily for three 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=0.054). The proportion of responders ( $\geq$ 50% reduction in the number of migraine days/month) was 38% (95% CI, 22% to 55%) in the TENS group and 12% (95% CI, 1% to 23%) in the sham group (p=0.014). The number of migraine attacks from the run-in period to the 3-month evaluation was significantly lower for the active TENS group (decrease of 0.82 in the TENS group vs 0.15 in the sham group, p=0.044). Moreover, the number of headache days was lower in the TENS group reported a 36.6% reduction in the number of acute antimigraine drugs taken compared with a 0.5% reduction in the sham group (p=0.008). 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 postmarketing 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

An 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.<sup>45,</sup> 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 ten weeks (p<0.05). 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<0.05); these differences were significant except for the period between 15 weeks 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 ten 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

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).<sup>46,</sup> 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<0.050); 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**

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).<sup>47,</sup>

Effects of TENS combined with ultrasound were more positive in an 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 three sessions per week for four consecutive weeks of low-frequency, high-intensity burst TENS combined with ultrasound, medium-frequency, low-intensity

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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.<sup>48,</sup>

## **Mixed Chronic Pain Conditions**

An overview of Cochrane review by Gibson et al (2019) evaluated the evidence from 8 Cochrane reviews that consisted of 51 RCTs which compared TENS vs 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.<sup>49,</sup>

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; it included 25 RCTs (total n=1281 patients).<sup>7,17,</sup> 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).<sup>50</sup> Data were converted to percentage improvement in VAS scores, then transformed into standardized differences (a continuous measure that adjusts for variability in different outcome measures). Based on the combined standardized difference, 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 (12=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 (Devo et al [1990],<sup>51</sup>, Machin et al [1988]<sup>52,</sup>) 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 Page 12 of 27

data were transformed, and the clinical significance of the results, the results from this metaanalysis are considered inconclusive.

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 (10-12 h/d) of TENS (58%) than after use of a sham device (43%).<sup>53,</sup> 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), greater satisfaction with TENS in the group of patients with bone and soft tissue injury or visceral pain (74% vs 48%, n=34, 31, both respectively).<sup>54</sup>, The nearly 50% patient satisfaction rating in the sham control group suggests a strong nonspecific effect with this treatment protocol. Survival analysis over the course of one year revealed no significant difference in the percentage of patients satisfied with the treatment (willing to continue).55, 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. This study supported a sustained placebo effect.

## Section Summary: TENS for Chronic Pain

Available evidence indicates that TENS can improve chronic intractable pain in some patients. 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.

## **TENS For Acute Pain**

## **Clinical Context and Test 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 PICOs were used to select literature to inform this review.

#### Patients

The relevant populations of interest are individuals who suffer from acute pain conditions (e.g., surgical, musculoskeletal, labor, and mixed pain conditions).Patients with acute pain are actively managed by surgeons, obstetricians, physical therapists, and primary care physicians in an outpatient setting.

## 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 two, four, and six weeks is of interest to monitor outcomes.

#### **Study Selection Criteria**

Methodologically credible studies were selected using the principles outlined for indication 1.

## Injury

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).<sup>56,</sup>

## Surgical Pain

## Systematic Reviews

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.<sup>57,</sup> 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=0.02). 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 large RCT on postsurgical TENS.<sup>58,</sup> 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 six 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.<sup>59,</sup> For the primary outcome (reduction of opioid intake), no significant difference was observed between active and placebo TENS groups (p=0.60); 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.

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 an 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.<sup>60.</sup> 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.<sup>61.</sup> 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.<sup>62.</sup> Pulmonary function (vital capacity, cough peak flow) was also significantly better in the active TENS arm. In a single-blinded randomized trial with 42 patients, Silva et al (2012) assessed the analgesic effect of TENS after laparoscopic cholecystectomy.<sup>63.</sup> Pain improved by a median of 2.4 points of 10 after TENS compared with 0.4 points after placebo treatment. The relative risk of nausea and/or emesis was 2.2 times greater for patients in the placebo group. In a double-blind RCT of 40 patients undergoing inguinal herniorrhaphy, DeSantana et al (2008)

reported on 2, 30-minute sessions of TENS at 2 and 4 hours after surgery (vs sham) reduced both analgesic use and pain scores when measured up to 24 hours postsurgery.<sup>64</sup>,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 min a day to semi-supervised exercise did not significantly improve VAS scores.<sup>65,</sup>

It is unclear whether the differences in findings between the Rakel et al (2014) RCT and the smaller RCTs were due to increased risk of bias in small studies, or to the differences in the time since surgery or type of surgery. One could conclude with relative certainty that TENS has no greater effect than a placebo on pain measured at least one day following total knee arthroplasty.

## Bone Marrow Sampling

Tucker et al (2015) reported on a double-blind RCT of TENS administered during bone marrow sampling in 70 patients.<sup>66,</sup> There was no significant difference in a numeric pain score between patients who received strong TENS impulses and the control group that received TENS just above the sensory threshold as reported immediately after the procedure (5.6 vs 5.7, respectively). Over 94% of patients in both groups felt they benefited from TENS.

#### Low Back Pain

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 LBP, evidence was inconclusive in the other two RCTs. Review authors concluded that, overall, the evidence is insufficient to support or refute the use of TENS for acute LBP.<sup>67,</sup>

#### Dysmenorrhea

One Cochrane review by Proctor et al (2002) assessed 9 small, controlled trials and found high-frequency TENS to be effective for the treatment of dysmenorrhea.<sup>20,</sup>

#### Hysteroscopy

Lison et al (2017) published an 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.<sup>68,</sup> Unlike other studies of the use of TENS in hysterectomy, the trial used varying high-fixed TENS (fluctuating between 80 and 100 Hz) and isolated the relief of pain by prohibiting oral medications taken before the procedure. 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<0.001). 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<0.001 and p=0.001, 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. In addition, the study excluded patient anxiety as an outcome, focusing instead on pain and patient satisfaction.

## Labor and Delivery

## Systematic Reviews

A Cochrane review by Dowswell et al (2009) included 19 studies with 1671 women in labor.<sup>8,</sup> Overall, there was little difference in pain ratings between TENS and control groups, although women receiving TENS to acupuncture points were less likely to report severe pain (relative risk,

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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 2010.69, 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 delivery or cesarean delivery but before the administration of TENS, the placebo and active groups did not significantly differ in VAS scores or verbal numeric scale scores. However, after active TENS in the cesarean group, there was a significant reduction in VAS (p<0.001) and verbal numeric scale (p<0.001) 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=0.022) and verbal numeric scale (p=0.005) 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=0.83), but, in the cesarean arm, the active treatment group had a significant reduction in analgesic need (p=0.006). 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.<sup>70,</sup>

## 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).<sup>71,</sup> Nineteen RCTs involving 1346 participants at entry were included. Data on pain intensity were pooled for 6 trials, showing a mean difference of -24.62 mm on a 100-mm VAS in favor of TENS, with significant heterogeneity between the trials. Data on the proportion of participants achieving at least 50% reduction in pain 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).<sup>72.</sup> A literature search identified 4 sham-controlled randomized trials of TENS (total 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<0.001). The 4 studies had significant heterogeneity (I2=94%). The difference between final pain scores for TENS and sham was 33 mm (95% CI, 21 to 44 mm; p<0.001). 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<0.001). 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.<sup>73,</sup> 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.

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## **Tennis Elbow**

A multicenter RCT of TENS as an adjunct to primary care management for tennis elbow was reported by Chesterton et al (2013).<sup>74,</sup> 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) vs 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=0.31) between the 2 groups at 6 weeks, 6 months (-0.20; 95% CI, -0.81 to 0.42; p=0.526), or 12 months (0.45; 95% CI, -0.15 to 1.06; p=0.139). However, adherence to exercise and TENS was very poor, with only 42 (35%) meeting prior adherence criteria. Perprotocol analyses only showed a statistically significant difference in favor of TENS at 12 months (p=0.030).

## Section Summary: TENS 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. For the treatment of pain after total knee arthroplasty, two large RCTs found no benefit of TENS compared with sham TENS. A subsequent systematic review found that TENS reduced pain in the immediate postoperative period (24 hours) after total knee arthroplasty compared with a control intervention, however, neither the intensity nor optimal duration time for TENS have been established. 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. For the relief of pain during office-based hysteroscopy, an RCT found decreased pain and higher patient satisfaction in patients receiving TENS compared with placebo or control.

## 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. The 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 a meaningful 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. The 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. For the treatment of pain after total knee arthroplasty, two large RCTs found no benefit of TENS compared with sham TENS. A subsequent systematic review found that TENS reduced pain in the immediate postoperative period (24 hours) after total knee arthroplasty compared with a control intervention, however, neither the intensity nor optimal duration time for TENS have been established. For the prevention of migraine headaches, a

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small RCT reported a greater proportion of patients achieving at least a 50% reduction in migraines with TENS than with sham placebo and modest reductions in the number of total headache and migraine days. This manufacturer-sponsored trial needs corroboration before conclusions can be made about the efficacy of TENS for preventing migraine headaches. For the relief of pain during office-based hysteroscopy, an RCT found decreased pain and higher patient satisfaction in patients receiving TENS compared with placebo or control. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Supplemental Information

## 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 from Blue Cross Blue Shield Association, input was received from 3 physician specialty societies and 5 academic medical centers 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 from Blue Cross Blue Shield Association, input was received from 4 physician specialty societies (5 reviewers) and 3 academic medical centers (4 reviewers) 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 European Headache Federation

The European Headache Federation (2013), citing concerns about an ineffective sham procedure for TENS in headache methodology studies and the overall limited level of evidence, recommended that there was insufficient evidence for the use of TENS in headache prophylaxis and to abort an acute headache.<sup>75,</sup>

## Osteoarthritis Research Society International

Guidelines from the Osteoarthritis Research Society International (2014) recommended that TENS was inappropriate for use in patients with multijoint osteoarthritis; moreover, the guidelines suggested that TENS has an uncertain value for the treatment of knee-only osteoarthritis pain.<sup>76</sup>

## National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on adult cancer pain (v.1.2018) indicate that nonpharmacologic interventions, including TENS, may be considered in conjunction with pharmacologic interventions as needed (category 2A).<sup>72,</sup>

## National Cancer Institute

National Cancer Institute's Physician Data Query identifies TENS as a potential other nonpharmacological modality for pain control for postthoracotomy pain syndrome.<sup>77,</sup>

## North American Spine Society

The North American Spine Society (2011) 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

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cervical radiculopathy from degenerative disorders.<sup>78,</sup> 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

The American Academy of Neurology (2010) published an evidence-based review of the efficacy of TENS for the treatment of pain in neurologic disorders.<sup>24,</sup> 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 two class I studies), and that TENS should be considered for the treatment of painful diabetic neuropathy (level B, probably effective, based on two class I studies).

## American Society of Anesthesiologists et al

The practice guidelines from the American Society of Anesthesiologists and American Society of Regional Anesthesia and Pain Medicine (2010) 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).<sup>79,</sup>

## National Institute for Health and Care Excellence

The NICE (2016) 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.<sup>80,</sup> This guidance recommended against TENS as a treatment.

The NICE (2014) guidance on osteoarthritis care and management in adults indicated that TENS be considered "as an adjunct to core treatments for pain relief."<sup>81,</sup>

The NICE (2017) guidance on intrapartum care recommended against the use of TENS for "established labour."<sup>82,</sup>

## American Congress of Obstetricians and Gynecologists

The ACOG guidelines (2007) for women's health care state that methods of neurostimulation, such as TENS, acupuncture, and massage, were based on the gate theory of pain control.<sup>83,</sup> These treatments can be useful for pain control, particularly when the pain is severe. The guidelines recommended that because different methods of treatment work by different mechanisms (e.g., relaxation techniques, TENS, physical therapy, vocational rehabilitation, biofeedback), the use of multiple treatment modalities in synergy should be considered.

The ACOG guidelines (2004) on chronic pelvic pain found that clinical trials evaluating the efficacy of acupuncture, acupressure, and TENS therapies have been performed only for primary dysmenorrhea, not for nonmenstrual pelvic pain.<sup>84,</sup> The guidelines recommended that acupuncture, acupressure, and TENS therapies be considered to decrease the pain of primary dysmenorrhea.

The ACOG guidelines (2019) on labor and delivery found that TENS may "help women cope with labor more than directly affect pain scores."<sup>85,</sup>

## American College of Physicians

The American College of Physicians (2017) published guidelines on noninvasive therapies for acute and low back pain.<sup>86</sup>. 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.

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### **European Federation of Neurological Societies**

The European Federation of Neurological Societies (2007) published guidelines on neurostimulation for neuropathic pain.<sup>87,</sup> The guidelines did not offer conclusive recommendations, with only approximately 200 patients with different diseases, based on studies using different parameters and comparators, and having variable results. The societies concluded that standard high-frequency TENS is possibly (level C) better than placebo and probably (level B) worse than acupuncture-like or any other kind of electrical stimulation.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

The Centers for Medicare & Medicaid Services currently have a number of national coverage decisions on TENS.<sup>88-92,</sup> The different coverage decisions address the use of TENS in the treatment of chronic intractable pain, noncoverage of TENS for chronic low back pain except to conduct research for said indication, and coverage for acute postoperative pain.

## **Ongoing and Unpublished Clinical Trials**

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

NCT No.	Trial Name		Completion Date
Ongoing			
NCT02642796	Comparison of the Efficacy of Two Different Transcutaneous Electrical Nerve Stimulation Application Sites in Reducing Postoperative Pain After Hip Fracture Surgery	120	Mar 2020 (ongoing)
NCT04020861	Photobiomodulation Therapy and Transcutaneous Electrical Nerve Stimulation on Chronic Neck Pain Patients: a Protocol of a Randomized Clinical Trial	`44	May 2020
NCT03990441	Analgesic Efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) Versus Placebo During the First Stage of Labor. Double-blind Randomized Clinical Trial	46	March 2020
NCT03925129	A Randomized, Placebo-Controlled Trial of Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Management With Medication Abortion Through 70 Days' Gestation	40	Feb 2020
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
Unpublished			
NCT03072888	The Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on Pain and Quality of Recovery After Abdominal Hysterectomy	50	May 2017 (completed)
NCT01641471a	Prospective Evaluation of Transcutaneous Electrical Nerve Stimulation (TENS) for Pain Relief Following Total Knee Arthroplasty (TKA)	116	Jun 2015 (completed)
NCT01875042	Does Transcutaneous Electrical Nerve Stimulation (TENS) Affect Pain and Function in Patients With Osteoarthritis of the Knee? ETRELKA, a Randomised Controlled Trial	220	Jan 2015 (completed)
NCT: national c	clinical trial.		

#### Table 1. Summary of Key Trials

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

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## **Documentation for Clinical Review**

## Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - o Multidisciplinary evaluation
  - Pain assessment including nature, duration, and perceived intensity of pain (if applicable)
- Prescription for make and model of the device requested
- Prior and ongoing treatments (including type and duration, and medications)
- Proposed use of device (including frequency and duration of treatment)
- Clinical summary for continued use of a TENS unit (if applicable):
  - o Any ongoing pain control requirements (e.g., medication and other modalities)
  - o Perceived pain intensity with and without TENS (e.g., visual analog scale [VAS])
  - TENS usage on a daily basis (frequency and duration of application)

## Post Service

- Procedure report(s)
- Product invoice

## Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

## MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Туре	Code	Description	
CPT®	None		
HCPCS	A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)	
	A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient	
	E0720	Transcutaneous electrical nerve stimulation (TENS) device, two-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)	

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action		
04/03/2009	<ul> <li>Policy Revision <ul> <li>Transcutaneous Electrical Nerve Stimulation (TENS) for the Treatment of Pain</li> <li>Interferential Stimulation</li> </ul> </li> <li>Developed new policy: <ul> <li>High-voltage Galvanic Stimulation</li> <li>Bioelectric Therapy</li> <li>Microcurrent Electrical Nerve Stimulation</li> </ul> </li> <li>Adopted: <ul> <li>H-wave Electrical Stimulation</li> <li>Percutaneous Electrical Nerve Stimulation (PENS) or Percutaneous Neuromodulation Therapy</li> <li>Sympathotic Thorapy</li> </ul> </li> </ul>		
10/29/2010	Coding Update		
03/13/2012	Coding update		
01/25/2013	Policy title change from Electrical Stimulation for Pain with position change		
04/11/2013	Policy revision with position change		
04/30/2015	Coding Update		
07/31/2015	Policy title change from Electrical Stimulation for Pain and Other Conditions Policy revision with position change		
09/01/2016	Policy revision without position change		
10/01/2017	Policy revision without position change		
01/01/2018	Policy revision without position change Coding Update		
01/01/2019	Coding update		
02/01/2019	Policy revision without position change		
02/01/2020	Annual review. No change to policy statement. Literature review updated.		

## **Definitions of Decision Determinations**

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions,

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but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.