MP 1.01.05  Transcutaneous Electrical Nerve Stimulation (TENS)

Medical Policy

Section  
Durable Medical Equipment

Original Policy Date  
12:2013

Last Review Status/Date  
12:2013

Issue  
12:2013

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Description

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

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

Percutaneous electrical nerve stimulation (PENS) (policy No. 7.01.29) is similar to TENS but uses microneedles that penetrate the skin instead of surface electrodes. Interferential stimulation (policy No. 1.01.24) uses a modulated waveform for deeper tissue stimulation and 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 received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) process. Marketing clearance via the 510(k) process does not require data regarding clinical efficacy; these devices are considered substantially equivalent to predicate devices marketed in interstate commerce prior to May 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified and do not require approval of a premarket approval application (PMA).
Policy

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 the following conditions have been met:

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

Continued use of transcutaneous electrical nerve stimulation (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 the following conditions have been met:

- Efficacy has been demonstrated in an initial therapeutic trial (see policy guidelines); AND
- 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.

TENS is considered investigational for the management of acute pain (e.g., postoperative or during labor and delivery).

The use of TENS for any other condition, including the treatment of dementia, is considered investigational.

Policy Guidelines

Refractory chronic pain is defined in this policy 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 TENS unit, including the frequency and duration of treatment.

Clinical summary of the trial to determine efficacy should include:

- Perceived intensity of pain with and without TENS (e.g., 2 point or 30% improvement in visual analog scale [VAS]);
- Ongoing medication requirements for pain relief (if any);
- Other modalities (if any) in use for pain control;
• Actual use of TENS on a daily basis (frequency and duration of application).

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.

Rationale

This policy was originally based on a 1996 TEC Assessment of transcutaneous electrical nerve stimulation (TENS) for the treatment of chronic and postoperative pain, which concluded that the evidence did not clearly show that the effects of TENS exceeded placebo effects. (1) An updated literature search in October 2002, identified several Cochrane reviews of TENS. (2-7) One of the reviews, last amended in June 2000, addressed chronic pain resulting from a variety of conditions (e.g., osteoarthritis of the knee, rheumatoid arthritis of the wrist, pancreatitis, myofascial trigger points, chronic back pain, temporomandibular joint pain, and a variety of nociceptive and neuropathic causes of pain). (2) A total of 19 randomized trials were judged as meeting study selection criteria, but due to heterogeneity of methods and inability to extract sufficient dichotomous pain outcomes data, it was concluded that meta-analysis was not possible and the review of evidence was inconclusive. The trials reviewed did not indicate which stimulation parameters were most likely to provide pain relief or answer questions about long-term effectiveness. The authors suggested a need for large, multicenter, randomized, controlled trials (RCT) of TENS in chronic pain.

In a 2004 literature review update, 2 additional Cochrane reviews were identified along with several RCTs on the use of TENS. (8, 9) Neither the Cochrane reviews nor any of the RCTs identified were sufficient to alter the previous conclusions. The authors of the Cochrane reviews concluded that the evidence was inadequate to draw conclusions about the effects of TENS. The policy update in 2007 examined the Cochrane reviews on TENS that had been published over the previous 7 years. (2-12) Three additional Cochrane reviews were published or updated in 2008, addressing the topics of TENS for cancer pain, chronic low back pain, and other chronic pain conditions. (13-15) Another 5 Cochrane reviews were published or updated between 2009 and June 2010 on the topics of acute pain, labor pain, neck pain, phantom limb pain, and osteoarthritis of the knee. (16-20) In 2010, the American Academy of Neurology (AAN) published an evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders, including low back pain and diabetic peripheral neuropathy. (21) The evidence on TENS for specific conditions is described below.

Chronic Pain

Low Back Pain

Cochrane reviews from 2005, updated in 2008, concluded that there is limited and inconsistent evidence for the use of TENS as an isolated treatment for low back pain. (10, 13) For the treatment of chronic low back pain, 4 high-quality RCTs (585 patients) met the selection criteria. (18) There was conflicting evidence about whether TENS reduced back pain, and consistent evidence from 2 of the trials (410 patients) indicated that it did not improve back-specific functional status. The review concluded that the evidence available at this time did not support the use of TENS in the routine management of chronic low back pain.
In 2010, the American Academy of Neurology (AAN) published an evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders. (21) 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 to TENS-sham with 4 or 6 weeks of treatment. Although both studies were adequately powered to find at least a 20% difference in pain reduction by visual analog scale (VAS), after correction for multiple comparisons, no significant benefit was found for TENS compared to TENS-sham. In 2 of the 3 class II studies, no significant differences were found between TENS and TENS-sham. In the third class II study, benefit was found in 1/11 patients treated with conventional TENS, 4/11 treated with burst-pattern TENS, and 8/11 treated with frequency-modulated TENS.

Overall, evidence was found to be conflicting. Because the class I studies provide stronger evidence, the AAN considered the evidence sufficient to conclude that TENS is ineffective for the treatment of chronic low back pain.

**Diabetic Peripheral Neuropathy**

The AAN’s 2010 evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders identified 2 class II studies comparing TENS to sham TENS and 1 class III study that compared TENS to high-frequency muscle stimulation for patients with mild diabetic peripheral neuropathy. (21) The studies found a modest reduction in VAS for TENS compared to sham, with a larger proportion of patients feeling benefit with high-frequency muscle stimulation compared to TENS. The authors concluded that on the basis of these 2 class II studies, TENS is probably effective in reducing pain from diabetic peripheral neuropathy, although there are presently no studies comparing TENS to other treatment options.

A small RCT from 2011 found no difference between microcurrent TENS (micro-TENS) compared to sham in 41 patients with diabetic peripheral neuropathy. (22) In this study, current was applied at an intensity of 30-40 microAmps rather than the usual intensity of 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 of 30% reduction in the neuropathic pain score. The median Pain Disability Index was reduced to a similar extent in the TENS group (23%) and the sham group (25%).

**Cancer Pain**

For the 2008 Cochrane review on TENS for cancer pain, only 2 RCTs (total of 64 participants) met the selection criteria for inclusion in the systematic review. (14) There were no significant differences between TENS and placebo in the included studies. One RCT found no differences between TENS and placebo for pain secondary to breast cancer treatment. The other RCT examined acupuncture-type TENS in palliative care patients but was underpowered. Results of the review were considered inconclusive due to a lack of suitable RCTs. A 2012 update of the Cochrane review identified one additional RCT (a feasibility study of 24 patients with cancer bone pain) that met selection criteria. (23) The small sample sizes and differences in patient study populations of the 3 RCTs prevented meta-analysis. Results on TENS for cancer pain remain inconclusive.

**Osteoarthritis of the Knee**
A Cochrane review from 2000 found TENS and acupuncture-like TENS to be more effective than placebo for the treatment of knee osteoarthritis but indicated that due to heterogeneity of the included studies, more well-designed trials with adequate numbers of participants were needed to conclude effectiveness. (7) An updated Cochrane review from 2009 identified 14 additional trials, resulting in the inclusion of 18 small trials in 813 patients. (20) Eleven trials used TENS, 4 used interferential current stimulation, 1 trial used both TENS and interferential current stimulation, and 2 trials used pulsed electrostimulation. The methodologic quality and the quality of reporting were found to be poor. In addition, 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. The predicted difference in pain scores between electrostimulation and control was 0.2 cm on a 10-cm VAS. The effect of electrostimulation on function was small but potentially clinically relevant, and the evidence appeared to be less affected by biases associated with small sample size. Overall, the evidence on TENS for pain relief in patients with osteoarthritis of the knee was considered to be inconclusive.

In 2007, Bjordal et al. published a meta-analysis on the short-term efficacy of physical interventions for osteoarthritic knee pain. (24) Included in the review were 11 studies (259 subjects on active therapy) using TENS, acupuncture-like TENS (AL-TENS), or interferential stimulation; 9 of the 11 studies were included in the meta-analysis reviewed above. Combined data revealed a 19-mm improvement in VAS over placebo (a “slight improvement”), with a confidence interval ranging from 10 mm (a “minimal perceptible improvement”) to 28 mm (above the 20 mm threshold of an “important improvement”). These results are similar to an earlier Cochrane review (overlap of 6 studies) on the use of TENS or AL-TENS for osteoarthritis of the knee. (7) The inclusion of 2 studies on interferential stimulation (with an unweighted average improvement in VAS of 34 mm over placebo) may also have increased the magnitude of the effect. Considering that the potential for publication bias is high when combining a number of small studies in a meta-analysis (particularly when the effect is small), evidence of short-term relief of chronic musculoskeletal pain remains weak. Results from these positive meta-analyses must also be balanced against other systematic reviews of musculoskeletal pain syndromes that found mixed and inconclusive results.

Rheumatoid Arthritis

Cochrane reviews from 2002 and 2003 concluded that results in patients with rheumatoid arthritis were conflicting. (4, 8)

Phantom Limb Pain

A 2010 Cochrane review found no RCTs on TENS for phantom pain and stump pain following amputation. (19) The authors concluded that the published literature on TENS for phantom limb pain in adults lacks the methodologic rigor and robust reporting needed to confidently assess its effectiveness and that further RCT evidence is required.

Neck Pain

Cochrane reviews from 2005 and 2009 evaluated various types of electrotherapy for neck pain. (12, 18) Eighteen small trials (total of 1,043 subjects with neck pain) with 23 comparisons were included in the most recent (2009) systematic review. The authors found very low-quality evidence that TENS is more effective than placebo.

Pain Following Stroke
Evidence on the efficacy of TENS for shoulder pain after stroke was considered inconclusive in another Cochrane review from 2000. (5)

Headache

A 2004 Cochrane review assessed noninvasive physical treatments for chronic/recurrent headache. (11) Twenty-two studies with a total of 2,628 patients (age 12 to 78 years) met the inclusion criteria. The review included 5 types of headache and various noninvasive treatments including spinal manipulation, electromagnetic fields, and a combination of TENS and electrical neurotransmitter modulation. Combination TENS and electrical neurotransmitter modulation was found to have weak evidence of effectiveness for migraine headache. Either the combination treatment or TENS alone had weak evidence of effectiveness for the prophylactic treatment of chronic tension-type headache. The authors concluded that although these treatments appear to be associated with little risk of serious adverse effects, the clinical effectiveness and cost-effectiveness of noninvasive physical treatments requires further research using scientifically rigorous methods.

Mixed Chronic Pain Conditions

A 2008 Cochrane review updated the evidence on the use of TENS for the treatment of various chronic pain conditions, including rheumatoid arthritis with wrist pain, temporomandibular joint dysfunction, multiple sclerosis with back pain, osteoarthritis with knee pain, neuropathy, pancreatitis, and myofascial trigger points, and included 25 RCTs (1,281 patients). (2, 15) Due to heterogeneity, meta-analysis was not possible; slightly more than half of the studies found a positive analgesic outcome in favor of active TENS treatments. The authors concluded that the 6 studies added since the last version of this review did not provide sufficient additional information to change the conclusions and that the published literature lacks 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 included 38 randomized controlled comparisons (1,227 patients from 29 publications) of trans- or percutaneous electrical nerve stimulation (ENS) for chronic musculoskeletal pain, using any stimulation parameters on any location (e.g., back, neck, hip, knee). (25) The data were converted to a percentage improvement in VAS scores, then transformed into standardized mean differences (a continuous measure that adjusts for variability in different outcome measures). Based on the combined standardized difference, the authors concluded that TENS provided pain relief “nearly three times” the pain relief provided by placebo. There are a number of sources of bias in the analysis that seriously limit interpretation of the results. First, the heterogeneity of the individual study results (I^2, 82%) raises questions about the appropriateness of combining these studies in a meta-analysis (see previous discussion regarding the decision to not combine studies for the 2000 and 2008 Cochrane reviews on chronic pain). Further limiting interpretation is the transformation of data to standardized effect size, which appears to have led to discrepant effect sizes of otherwise similar results. For example, comparison of the untransformed and transformed data shows that while 2 of the included trials (Deyo et al. 1990 (26) and Machin et al. 1988 (27)), found similar percentage point differences in VAS between active and control groups (5% and 8%, respectively), the standardized effect sizes are not equivalent.

Positive standardized effect sizes from data that are not statistically or clinically significant (e.g., 47% vs. 42% change from baseline in Deyo et al.) also raises concerns about the appropriateness of the data transformation. Inclusion of poor-quality studies is an additional
concern, since several of the studies with the greatest effect sizes reported drop-out rates exceeding 25%. Furthermore, bias for publication of small positive studies may not have been adequately addressed, since the “Fail-safe N” method used to assess publication bias is problematic. Another major limitation in interpretation of this meta-analysis is the absence of information about whether ENS results 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 indicates that there was less than a 15% difference between the ENS and placebo groups (with an average difference of 4%) for 13 of the 38 (34%) comparisons. The small effect observed in many of these small studies raises further questions about the contribution of publication bias to the meta-analysis. Also at issue is the relative contribution of percutaneous ENS (PENS), since meta-regression found PENS to be more effective than TENS. Given the substantial uncertainty regarding the appropriateness of the studies included and how the data were transformed, combined with questions regarding the clinical significance of the results, results from this meta-analysis are considered inconclusive.

A 2006 randomized sham-controlled trial (163 patients with diverse pain states) by Osterhof et al. reported that although no differences in VAS pain scores were observed, more patients were satisfied (i.e., willing to continue treatment) following 10 days (10-12 hours/day) of TENS (58%) than following use of a sham device (43%). (28) Analysis of the results by type of pain (osteoarthritis-related, 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 injury of bone and soft tissue or visceral pain (74% vs. 48%, n=34, 31, both respectively). (29) 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 who were satisfied with treatment (willing to continue). (30) At 1-year follow-up, 30% of the patients from the TENS group and 23% of the sham TENS group remained satisfied with treatment (not significantly different). For the satisfied patients, there was no significant difference between the TENS and sham group in the magnitude of improvement (61.7% vs. 63.9%), pain intensity (change in VAS of 27.7 vs. 29.4), disability (12.4 vs. 12.2), or perceived health status (5.2 vs. 5.8, all respectively). This study supports a sustained placebo effect.

Acute Pain

Injury

One double-blind randomized, sham-controlled trial found that during emergency transport of 101 patients, TENS reduced post-traumatic hip pain with a change in VAS from 89 to 59, whereas the sham-stimulated group remained relatively unchanged (86 to 79). (31)

Surgical Pain

In a double-blind study, 40 patients undergoing inguinal herniorrhaphy were randomly assigned to active or placebo TENS for postsurgical pain. (32) Pain scores measured prior to the first treatment were 5.2 on a 10-point scale for the active TENS group and 5.3 for the placebo TENS group. Two 30-minute sessions of TENS at 2 and 4 hours after surgery reduced both analgesic use and pain scores measured up to 24 hours after surgery (mean pain score of 0 vs. 3.4,
respectively). Blinding appears to have been maintained, as 95% of subjects from both groups reported that they would use TENS again in the future to treat their pain.

A single-blinded randomized trial with 42 patients assessed the analgesic effect of TENS after laparoscopic cholecystectomy. (33) Patients were treated with active or placebo TENS for 30 minutes within the first 24 hours after the operation. Pain, assessed by VAS before and immediately after treatment, improved by a median of 2.4 after TENS and 0.4 after placebo treatment. Pain, on an 11-point numerical scale, improved by a median of 3.0 after TENS and 0.7 after placebo. The relative risk of nausea and/or emesis was 2.17 times greater for patients from the placebo group.

Confirmation of these results is needed.

**Dysmenorrhea**

One 2002 Cochrane review of 9 small, controlled trials found high-frequency TENS to be effective for the treatment of dysmenorrhea. (6)

**Labor and Delivery**

A 2009 Cochrane review included 19 studies with 1,671 women. (17) Overall, there was little difference in pain ratings between TENS and control groups, although women receiving TENS to acupuncture points were less likely to report severe pain (risk ratio 0.41). The review found limited evidence that TENS reduces pain in labor and did not seem to have any impact (either positive or negative) on other outcomes for mothers or babies. The authors concluded that although it is not clear that TENS reduces pain, they thought that women should have the choice of using TENS in labor if they think it will be helpful.

**Mixed Acute Pain Conditions**

A 2009 Cochrane review 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 nonprocedure pain (e.g., postpartum uterine contractions and rib fractures). (16) Twelve RCTs involving 919 participants at entry were included. A meta-analysis could not be performed due to insufficient data, and the authors were unable to make any definitive conclusions about the effectiveness of TENS as an isolated treatment for acute pain in adults.

**Other**

**Dementia**

Efficacy of TENS for dementia was considered inconclusive in a Cochrane review from 2003. (9)

**Recovery From Stroke**

A 2011 systematic review included 15 randomized or quasi-randomized studies (446 patients) on the use of TENS to enhance motor recovery following stroke. (34) Although the methodologic quality was considered generally good, only 4 studies were large RCTs. In the majority of studies (9/15), the number of subjects receiving TENS was less than 15. Stimulation targets for the various studies included nerves, muscles, acupuncture points, and the entire hand or foot.
The majority of studies reported significant effects on at least one outcome measure, though the effect sizes were generally small and there were insignificant effects for many outcome measures. Meta-analysis could not be performed for most outcomes because of variability between studies and insufficient data. A moderate effect was determined for force production of ankle dorsiflexion (but not plantar flexion) and for the Timed Up and Go test (but not the 10-meter gait velocity test or the 6-minute walk test). Overall, results from studies of TENS after stroke are inconsistent.

**Clinical Input Received through 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.

**2009**

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

**2011**

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

**Summary**

Overall, evidence for the use of TENS from high-quality trials remains inconclusive for most indications. The available studies are not consistent on whether TENS improves outcomes, and the overall strength of the evidence is weak for all indications. On the other hand, there is strong clinical opinion that TENS can relieve chronic intractable pain in some patients, and there is support for its use in clinical guidelines by specialty societies. In order to best target TENS toward patients who will benefit, a short-term trial of TENS is appropriate, with continuation only in patients who show an initial improvement. Therefore, TENS may be considered medically necessary for the treatment of chronic pain if shown to be effective during a 30-day therapeutic trial.

**Practice Guidelines and Position Statements**

National Comprehensive Cancer Network (NCCN) clinical practice guidelines in oncology from 2011 indicate that nonpharmacologic interventions including TENS may be considered in conjunction with pharmacologic interventions as needed (Category 2A). (35)
National Cancer Institute (NCI) 2011 guidelines on pain state that noninvasive physical and psychosocial modalities can be used concurrently with drugs and other interventions to manage pain during all phases of treatment. Patients with mild-to-moderate pain may benefit from a trial of TENS to see if it is effective in reducing the pain. TENS is a low-risk intervention. (36)

The North American Spine Society (NASS) 2011 clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders discusses the role of ancillary treatments such as bracing, traction, electrical stimulation, acupuncture and transcutaneous electrical stimulation in the treatment of cervical radiculopathy from degenerative disorders. A consensus statement recommends that ozone injections, cervical halter traction and combinations of medications, physical therapy, injections and traction have been associated with improvements in patient-reported pain in uncontrolled case series. Such modalities may be considered, recognizing that no improvement relative to the natural history of cervical radiculopathy has been demonstrated. (37)

In 2010, the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) published an evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders. (38) The AAN concluded that TENS is not recommended for the treatment of chronic low back pain due to lack of proven efficacy (level A, established evidence from 2 class I studies), and that TENS should be considered for the treatment of painful diabetic neuropathy (Level B, probably effective, based on 2 class II studies).

2010 Practice guidelines from the American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine (ASRA) recommends that TENS should be used as part of a multimodal approach to pain management for patients with chronic back pain and may be used for other pain conditions (e.g., neck and phantom limb pain). (39) The ASA’s 1997 guidelines on chronic pain management recommended that an office or home trial of TENS should be considered as an early management option or as an adjunctive therapy because of its low complexity and low risk. (40)

The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) 2009 guidance on low back pain states that despite the long history of use of TENS for back pain, the quality of research studies is poor. (41) These guidelines have failed to recommend TENS as a treatment, not because of evidence that it does not work, but because there is no evidence that it is effective.

The United Kingdom’s National Collaborating Centre for Chronic Conditions and NICE 2008 guidance on osteoarthritis care and management in adults states that “there is evidence that TENS is clinically beneficial for pain relief and reduction of stiffness in knee osteoarthritis, especially in the short term. However, this was not shown in a community setting. There is no evidence that efficacy trails off over time, or that periodic use for exacerbations is helpful.....People with osteoarthritis should be encouraged to experiment with intensities and duration of application if the desired relief of symptoms is not initially achieved. This enables patients’ control of their symptoms as part of a self-management approach. A further follow-up visit is essential in allowing the health professional to check patients’ usage of TENS and problem solve. No adverse events or toxicity have been reported with TENS.”(42)

The United Kingdom’s National Collaborating Centre for Women’s and Children’s Health and NICE 2007 guidelines on intrapartum care state that there is high-level evidence that TENS is
not an effective analgesic in established labor, and there is no high-level evidence on the analgesic effect of TENS in the latent phase of labor. (43) NICE recommends that TENS should not be offered to women in established labor.

The American Congress of Obstetricians and Gynecologists (ACOG) 2007 guidelines for women's health care state that methods of neurostimulation, such as transcutaneous electrical nerve stimulation, acupuncture, and massage, are based on the gate theory of pain control. These treatments can be useful for pain control, particularly when the pain is severe. The guidelines recommend that since different methods of treatment work by way of different routes (e.g., relaxation techniques, transcutaneous electrical nerve stimulation, physical therapy, vocational rehabilitation, and biofeedback), the use of multiple treatment modalities in synergy should be considered.

The 2004 ACOG guidelines on chronic pelvic pain found that clinical trials evaluating the efficacy of acupuncture, acupressure, and transcutaneous nerve stimulation therapies had been performed only for primary dysmenorrhea, not for nonmenstrual pelvic pain. (44) The guidelines recommend that acupuncture, acupressure, and transcutaneous nerve stimulation therapies should be considered to decrease pain of primary dysmenorrhea.

The American Pain Society and American College of Physicians published guidelines on therapies for acute and low back pain in 2007. (45) No recommendations for TENS were made; the panel concluded that TENS had not been proven effective for chronic low back pain.

The European Federation of Neurological Societies published 2007 guidelines on neurostimulation for neuropathic pain. (46) The task force was not able to arrive at conclusive recommendations, with only approximately 200 patients with different diseases, in studies using different parameters and comparators, and with variable results. The task force concluded that standard high-frequency TENS is possibly (level C) better than placebo and probably (level B) worse than acupuncture-like or any other kind of electrical stimulation.

The American Geriatrics Society’s 2002 guideline on the management of persistent pain in older persons indicated that TENS offers temporary relief and can be used as adjunctive therapy. (47) This recommendation was based on expert opinion and descriptive studies; clinicians “may or may not follow the recommendation.”

The American Medical Directors Association created a guideline in 1999 on management of pain for elderly patients in the long-term care setting. Among complementary therapies, TENS is one for which “Although no scientific evidence supports the effectiveness of these therapies in elderly patients in the long-term care setting, they may be beneficial to some individuals.”

The Department of Defense, Veterans Health Administration, published clinical guidelines for the management of postoperative pain in May 2002. These guidelines indicate that TENS may be useful for postoperative pain relief for a variety of procedures and sites. Except for postoperative abdominal pain and pain from cholecystectomy, all of the recommendations are consensus-based. For postoperative abdominal pain and pain from cholecystectomy, the recommendations are based on at least one RCT and general agreement that TENS is acceptable.

**Medicare National Coverage**

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OF THE CAROLINAS, INC.
The Centers for Medicare and Medicaid Services (CMS) currently have the following national coverage decisions on TENS (48-52):

- National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13) (48)

TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit. Also see NCDs on Supplies Used in the Delivery of TENS and NMES (§160.13) and TENS for Acute Post-Operative Pain (§10.2).

- Decision Memo for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N) (52)

In June 2012, CMS determined that TENS is not reasonable and necessary for the treatment of chronic low back pain. However, to support further research on the use of TENS for chronic low back pain, CMS will provide coverage under evidence development for a period of 3 years after the publication of this decision.

- National Coverage Determination for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) (49)

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. Transcutaneous Electrical Nerve Stimulation (TENS)

This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of 1 month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS.) If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain.

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a
supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

- National Coverage Determination for Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13) (50)

TENS and/or NMES can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients’ skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

1. It has received permission or approval for marketing by the Food and Drug Administration;
2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and
3. One of the medical indications outlined below is met:
   - The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;
   - The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;
   - The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;
   - The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or
   - The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §160.3 unless:

1. The patient has a documented skin problem prior to the start of the trial period; and
2. The carrier’s medical consultants are satisfied that use of such an item is medically necessary for the patient.
National Coverage Determination for Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2) (51)

The use of TENS for the relief of acute post-operative pain is covered under Medicare. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery. TENS devices, whether durable or disposable, may be used in furnishing this service. When used for the purpose of treating acute post-operative pain, TENS devices are considered supplies. As such they may be hospital supplies furnished inpatients covered under Part A, or supplies incident to a physician’s service when furnished in connection with surgery done on an outpatient basis, and covered under Part B. It is expected that TENS, when used for acute post-operative pain, will be necessary for relatively short periods of time, usually 30 days or less. In cases when TENS is used for longer periods, contractors should attempt to ascertain whether TENS is no longer being used for acute pain but rather for chronic pain, in which case the TENS device may be covered as durable medical equipment as described in §280.13.

References:


<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>64550</td>
<td>Application of surface (transcutaneous) neurostimulator</td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td>93.39</td>
<td>Other physical therapy</td>
</tr>
<tr>
<td>ICD-9 Diagnosis</td>
<td></td>
<td>See ICD-9 diagnosis index – “Pain”</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E0720, E0730, E0731</td>
<td>TENS code range</td>
</tr>
<tr>
<td></td>
<td>A4595</td>
<td>Electrical stimulator supplies, 2 leads, per month (e.g., TENS, NMES)</td>
</tr>
<tr>
<td></td>
<td>A4630</td>
<td>Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient.</td>
</tr>
</tbody>
</table>

ICD-10-CM (effective 10/1/14)

This list is a representative list of chronic musculoskeletal and neuropathic pain diagnosis codes

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>G89.21-G89.8</td>
<td>Chronic pain, not elsewhere classified, code range</td>
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<tr>
<td></td>
<td>G89.4</td>
<td>Chronic pain syndrome</td>
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<tr>
<td></td>
<td>G90.50-G90.59</td>
<td>Complex regional pain syndrome I (CRPS I), code range</td>
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<td></td>
<td>M25.50- M25.579</td>
<td>Pain in joint, code range</td>
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<td></td>
<td>M54.10- M54.18</td>
<td>Radiculopathy, code range</td>
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<tr>
<td></td>
<td>M54.2</td>
<td>Cervicalgia</td>
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<td></td>
<td>M54.30-M54.32</td>
<td>Sciatica, code range</td>
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<td></td>
<td>M54.40-M54.42</td>
<td>Lumbago with sciatica, code range</td>
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<td>M54.5</td>
<td>Low back pain</td>
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<td></td>
<td>M54.6</td>
<td>Pain in thoracic spine</td>
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<tr>
<td></td>
<td>M54.81, M54.89</td>
<td>Other dorsalgia codes</td>
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<td></td>
<td>M54.9</td>
<td>Dorsalgia, unspecified</td>
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<tr>
<td></td>
<td>M79.1</td>
<td>Myalgia</td>
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<tr>
<td></td>
<td>M79.2</td>
<td>Neuralgia and neuritis, unspecified</td>
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<tr>
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<td>R52</td>
<td>Pain, unspecified</td>
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ICD-10-PCS (effective)

ICD-10-PCS codes are only used for inpatient care.

FirstCarolinaCare Insurance Company, Inc. is a wholly-owned subsidiary of FirstHealth.
services. There is no specific ICD-10-PCS code for the initiation of this therapy.

<table>
<thead>
<tr>
<th>Type of Service</th>
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<tbody>
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<td>Place of Service</td>
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