MEDICAL POLICY

POLICY TITLE	TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION
POLICY NUMBER	MP-6.020

Original Issue Date (Created):	**October 25, 2011**
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I. POLICY

Trial of Transcutaneous Electrical Stimulation (TENS)

A TENS trial may be considered **medically necessary** to establish efficacy when **ALL** of the following conditions have been met:

- Pain condition meets ALL of the following:
  - Refractory chronic (e.g., chronic musculoskeletal pain, or neuropathic pain)
  - Causes significant disruption of function
  - Unresponsive to at least 3 months of conservative medical therapy (including nonsteroidal anti-inflammatory medications, ice, rest and/or physical therapy)
- Trial meets ALL of the following:
  - Monitored by a physician
  - At least 30 days in duration

Continued use of Transcutaneous Electrical Stimulation (TENS)

Continued use of TENS may be considered **medically necessary** when ALL of the following conditions have been met:

- Pain condition meets ALL of the following:
  - Refractory chronic (e.g., chronic musculoskeletal pain, or neuropathic pain)
  - Causes significant disruption of function
- Results of initial therapeutic trial meets ALL of the following:
  - Efficacy has been demonstrated
  - Compliance has been demonstrated with the device used on a regular basis (i.e., daily or near daily use) throughout the trial period

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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.

Policy Guidelines

Supplies separate allowance will be made for replacement supplies when they are reasonable and necessary and are used with a covered TENS. Usual maximum utilization is:
• 2 TENS leads - a maximum of one unit of A4595 per month
• 4 TENS leads - a maximum of two units of A4595 per month.

If the use of the TENS unit is less than daily, the frequency of billing for the TENS supply code should be reduced proportionally. Replacement of lead wires (A4557) more often than every 12 months would rarely be reasonable and necessary.

Transcutaneous Electrical Stimulation (TENS) Garment
Form-fitting conductive garments may be considered **medically necessary** when ALL of the following conditions have been met:

- Pain condition meets TENs medically necessary criteria
- Garment received permission or approval for marketing by the FDA
- Prescribed by a physician

- Prescribed for ANY ONE of the following medical indications:
  - Area to be stimulated large or multiple sites and stimulation delivered so frequently it is not feasible to use electrodes, adhesive tape and lead wires
  - Areas inaccessible with use of electrodes, adhesive tape, and lead wires
  - Documentation of medical condition (i.e., skin problems) that preclude the application of electrodes, adhesive tape and lead wires

TENS is considered **investigational** for the management of acute pain (e.g., postoperative or during labor and delivery) as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

The use of TENS for any other condition, including the treatment of dementia and the prevention of migraine headaches is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:
MP- 6.045 Sympathetic Therapy for the Treatment of Pain
MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP-6.047 Interferential Stimulation for Treatment of Pain
MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
MP-6.049 H-Wave Electrical Stimulation
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy
MP-6.051 Neuromuscular and Functional Neuromuscular Electrical Stimulation

II. PRODUCT VARIATIONS

TOP

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N]	Capital Cares 4 Kids	[N]	Indemnity
[N]	PPO	[N]	SpecialCare
[N]	HMO	[N]	POS
[Y]	SeniorBlue HMO*	[Y]	FEP PPO**
[Y]	SeniorBlue PPO*		

*For Transcutaneous Electrical Nerve (TENS): Acute post-operative pain is a covered condition for TENS units. The need for a garment due to TENS site under a cast is also a covered indication. Refer to Durable Medical Equipment Regional Carrier (DMERC) Region A Local Coverage Determination (LCD) L11506 Transcutaneous Electrical Nerve Stimulators (TENS).

** Refer to FEP Medical Policy Manual MP-1.01.09 Transcutaneous Electrical Nerve Stimulation (TENS). The FEP Medical Policy manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND

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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).

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 is similar to TENS but uses microneedles that penetrate the skin instead of surface electrodes. Interferential stimulation uses a modulated waveform for deeper tissue stimulation and 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).

On March 11, 2014 FDA granted *de novo* 510(k) approval for marketing to Cefaly® (STX-med, Herstal, Belgium), which is a TENS device for the prophylactic treatment of migraine in patients 18 years of age or older. (1)

Transcutaneous Transducer Garment

Transcutaneous electrical nerve stimulation (TENS) or neuromuscular electrical stimulation (NMES) is usually delivered to patients through the use of electrodes applied to the skin surface. There may be times, however, when certain patients receive TENS or NMES treatment using a garment with conductive fibers that are separated from the patient's skin by layers of fabric. The conductive garment is worn as an alternative to the conventional TENS/NMES unit

IV. RATIONALE

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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. (2) An updated literature search in October 2002, identified several Cochrane reviews of TENS. (3-8) 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). (3) 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. (9, 10) 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. (3-13) 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. (14-16) 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. (17-21) 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. (22) The evidence on TENS for specific conditions is described below.

Chronic Pain

Chronic Pain: Low Back Pain

Cochrane reviews from 2005, updated in 2008, concluded that there is limited and inconsistent evidence for the use of TENS as an isolated treatment for low back pain. (11, 14) 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. (22) 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.

Keskin et al. reported a randomized controlled trial of TENS for pregnancy-related low back pain in 2012. (23) Seventy-nine patients were randomized to 6 TENS sessions over 3 weeks, a home exercise program, acetaminophen or a no-treatment control. In the control group, pain intensity increased in 57% of participants. Pain decreased in 95% of participants in the exercise group and all participants in the acetaminophen and TENS groups. VAS improved by a median of 4 points with TENS and by 1 point in the exercise and acetaminophen groups. In the control group, VAS worsened by 1 point. Roland-Morris Disability Questionnaire (RMDQ) scores indicated a significantly greater improvement in function in the TENS group (-8.5) compared to the control (+1), exercise (-3), and acetaminophen (-3) groups. This study is limited by the lack of a TENS-sham control.

Chronic 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. (22) 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. (24) 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%).

Chronic Pain: 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. (15) 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. (25) 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.

Chronic Pain: Fibromyalgia

A placebo-controlled cross-over RCT from 2013 investigated the effect of a single treatment of TENS in 41 patients with fibromyalgia. (26) Patients were blindly allocated to either no treatment, active TENS treatment or placebo treatment. Each of the treatment arms has therapy once per week for a 3-week period. Patients rated the average pain intensity before and after treatment on a 0 to 10 scale and found that pain with movement was less during active TENS when compared to placebo or no TENS ($P<0.05$). Patients also rated fatigue with movement and found that fatigue decreased with active TENS compared to placebo or no TENS, $P<0.05$ and $P<0.01$ respectively. Pressure pain threshold improvement was significantly greater in the active TENS group (30%, $P<0.05$) than placebo (11%) and no TENS (14%).

Another RCT published in 2013 investigated TENS in fibromyalgia. In this trial 39 patients were randomized into three 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 two active TENS devices at both

lumbar and cervical sites. (27) 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 to baseline. Patients who had a single site of active TENS reported a reduction in pain of 2.5 cm (P<0.05), and patients in the dual TENS group experienced the greatest reduction in pain of 4.2 cm (P<0.02). Consumption of medication for pain was also decreased significantly in the single TENS and dual TENS groups (P<0.05 and P<0.02 respectively). Sleep improvements were reported by 10 patients in the dual TENS group, 8 in the single TENS group, and by 4 patients in the placebo group. Fatigue increased for 3 patients in the placebo group, but decreased in 7 patients in the dual TENS group and 5 patients in the single TENS group. No adverse events were reported.

Chronic Pain: Refractory Chronic Pelvic Pain

An observational study of 60 men consecutively treated with TENS for refractory chronic pelvic pain syndrome was published in 2013.(28) TENS was performed at home for 12 weeks with participants keeping a pain diary for the calculation of VAS score. A successful treatment response was defined as a 50% or greater reduction in VAS at the 12-week endpoint and absolute VAS of <=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 43.6 months (95% CI, 33.2 – 56). After 12 weeks of treatment the mean VAS score decreased significantly (P<0.001) from 6.6 to 3.9. The quality of life as assessed by the National Institutes of Health Chronic Prostatitis Symptom Index improved significantly after 12 weeks of TENS treatment (P<0.001). No adverse events were reported.

Chronic Pain: Osteoarthritis of the Knee

A 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. (8) An updated Cochrane review from 2009 identified 14 additional trials, resulting in the inclusion of 18 small trials in 813 patients. (21) 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. (29) 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. (8) 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.

A 2012 trial randomized 75 patients with osteoarthritis pain to a single session of high-frequency TENS, low-frequency TENS, or placebo TENS. (30) Double-blind assessment during the treatment session found a significant increase in pressure pain threshold at the knee for both low- and high-frequency TENS. There was no effect of TENS on cutaneous mechanical pain threshold, heat pain threshold, or heat temporal summation. All 3 groups reported a reduction in pain at rest and during the timed up-and-go (TUG), and there were no differences in pain scores between groups. These results on pain scores suggest a strong placebo component of TENS treatment. There was no significant change in the time to perform the TUG in any of the groups.

An RCT comparing intra-articular hyaluronic acid (HA) injections with TENS for the management of knee osteoarthritis recruited 50 participants and was published in 2013. (31) Twenty-seven patients were randomized to HA and received one injection intra-articularly per week for five weeks. Twenty-three patients in the TENS group received a 20-minute session of TENS 3 times a week for 4 weeks. At 2 weeks follow-up, the TENS group exhibited a significantly greater improvement (P=0.03) than the HA group on the VAS pain scale (final score 4.17+-1.98 vs. 5.31+-1.78, respectively). No difference between the two groups was found at 2 months post treatment or at 3 months post treatment. Similarly the TENS group had a greater improvement on the Lequesne index at 2 weeks follow-up compared to the HA group (final score 7.78+-2.08 vs. 9.85+-3.54, respectively; P=0.01) and at 3 months follow-up (final score 7.07+-2.85 vs. 9.24+-4.04, respectively; P=0.03). Both treatment groups had significant improvements from baseline to 3 month on scores in walking time, patient global assessment and disability in activities in daily life. Only the TENS group improved in range of motion for the target joint.

In 2014, a randomized controlled trial of 224 participants with osteoarthritis of the knee assigned patients to one of three interventions: TENS (TouchTENS, TENScare, Surrey, United Kingdom) combined with education and exercise (n=73), sham TENS combined with education and exercise (n=74), or education and exercise alone (n=77). (32) Investigators and participants were blinded to treatment. Participants were treated for 6 weeks and directed to use the TENS device as needed for pain relief. WOMAC pain, function and total score improved significantly over time from baseline to 24 weeks but did

not vary between groups (P>0.05). TENS as an adjunct to exercise failed to elicit additional benefits.

Chronic Pain: Rheumatoid Arthritis

Cochrane reviews from 2002 and 2003 concluded that results in patients with rheumatoid arthritis were conflicting. (5, 9)

Chronic Pain: Phantom Limb Pain

A 2010 Cochrane review found no RCTs on TENS for phantom pain and stump pain following amputation. (20) 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.

Chronic Pain: 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.

A 2013 report by the Cochrane Collaboration reviewed the evidence on TENS for the treatment of chronic neck pain. (33) Four studies (two with a high risk of bias and two with a low risk of bias) compared TENS versus placebo for immediate pain relief. Three studies with a high risk of bias also compared TENS with electrical muscle stimulation, ultrasound, or manual therapy for the treatment of chronic neck pain. The treatment schedules and differing outcomes did not allow for pooling of results and group sizes were very small (7 to 43 participants) with varied results for TENS therapy. Overall the quality of this evidence is very low for TENS versus all comparators for the treatment of chronic neck pain.

Chronic Pain: Pain Following Stroke

Evidence on the efficacy of TENS for shoulder pain after stroke was considered inconclusive in another Cochrane review from 2000. (6)

Chronic Pain: Headache

A 2004 Cochrane review assessed noninvasive physical treatments for chronic/recurrent headache. (12) 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.

The Cefaly device (Cefaly, STX-med, Herstal, Belgium) is a TENS headband device intended for the prophylactic treatment of migraine in patients 18 years of age or older. (1) The clinical information on Cefaly was supplied by two studies, the Prevention of Migraine using the STS Cefaly (PREMICE), (34), and a European post-marketing surveillance study. (35) 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 three months and 59 (88%) completed the trial according to protocol. No serious adverse events occurred although 1 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 a 3 month period. Adherence was recorded by the TENS device. Ninety stimulation sessions were expected, but on average 55.5 sessions were completed by the active group and 49 were completed in the sham group. The primary outcome measures were changes in the number of migraine days and the percent of responders.

The authors present both ITT and per-protocol analyses, but only the ITT will be discussed. The reduction in the number of migraine days (run-in compared to 3 month) was 2.06 (95% CI -0.54 to -3.58) for the TENS group versus 0.32 (-0.63 to +1.27) for the sham group, this difference did not quite reach statistical significance (p=0.054). The proportion of responders (≥50% reduction in the number of migraine days/month) was 38% (95% CI 22-55%) in the TENS groups versus 12% (95% CI 1.0-23%) in the sham group (p=0.014). The number of migraine attacks from the run-in period to 3rd month was significantly lower for the active TENS group (decrease of 0.82 in the TENS groups versus 0.15 in the sham group, p=0.044). Number of headache days also was decreased in the TENS group compared to sham (decrease of 2.51 versus 0.15, p=0.041). Patients in the active TENS group reported a 36.6% reduced number of acute anti-migraine drugs taken compared to the 0.5% reduction in the sham group (p=0.0072).Severity of migraine days did not significantly differ between groups.

Participants rated their satisfaction with the treatment more highly in the active group (70.6%) than in the sham group (39%). During post-marketing surveillance 53% of 2,313 participants were satisfied with the device and willing to continue using it. Ninety-nine participants (4%) reported a complaint with the device although none were serious adverse events. The most commonly reported adverse events included: insomnia in 4 participants (0.2%), reversible forehead skin irritation in 5 participants (0.2%), headache after a TENS session in 12 participants (0.52%), sleepiness during a Cefaly session (0.52%), and a dislike of how the device felt leading to discontinuation in 29 participants (1.25%).

Chronic Pain: Mixed Chronic Pain Conditions

A 2008 Cochrane review updated the evidence on the use of TENS for the treatment of various chronic pain conditions, including rheumatoid arthritis with wrist pain, temporomandibular joint dysfunction, multiple sclerosis with back pain, osteoarthritis with

knee pain, neuropathy, pancreatitis, and myofascial trigger points, and included 25 RCTs (1,281 patients). (3, 16) 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). (36) 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 (I37) and Machin et al. 1988 (38)) found similar percentage point differences in VAS between active and control groups (5% and 8%, respectively), the standardized effect sizes are not equivalent.[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 (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 Oosterhof 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%). (39) 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). (40) 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). (41) 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

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). (42)

Acute Pain: Surgical Pain

In a double-blind study, 40 patients undergoing inguinal herniorrhaphy were randomly assigned to active or placebo TENS for postsurgical pain. (43) 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. (44) 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 in the placebo group.

Another single-blinded randomized trial of 55 patients assessed the analgesic effect of TENS after pancreatic resection. (45) All patients were treated according to a standard care protocol which postoperatively gave thoracal epidural analgesia infusion of Bupivacain of 1 mg/ml, Fentanyl 2µg/ml and Adrenaline 2µg/ml. When the infusion was terminated patients were treated with either sham TENS or active TENS treatment which was regulated by the patient with the only rule being that each session's duration be at least 30 minutes. The majority of participants (64%) dropped out and only 9 active TENS and 11 sham TENS participants were available for analysis. No differences were identified in additional analgesic consumption or pain estimations 24 hours after discontinuing epidural analgesia.

This evidence for treatment of acute post-surgical pain is insufficient to determine whether TENS improves outcomes for this group; further high quality trials are needed.

Acute Pain: Dysmenorrhea

One 2002 Cochrane review of 9 small, controlled trials found high-frequency TENS to be effective for the treatment of dysmenorrhea. (7)

Acute Pain: Labor and Delivery

A 2009 Cochrane review included 19 studies with 1,671 women. (18) 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.

A placebo-controlled, randomized trial of TENS assessed 200 women who gave birth between January 2010 and July 2010. (46) One hundred women who gave birth vaginally were allocated to either active TENS or sham TENS in a 1:1 ratio; this same assignment was performed for 100 women who gave birth by cesarean section. TENS was performed once for 30 minutes after childbirth was completed. After vaginal delivery or cesarean section but before administration of TENS, the placebo and active groups did not significantly differ in VAS score or VNS score. However, after active TENS in the cesarean group there was a significant reduction in VAS score ($P<0.001$) and VNS score ($P<0.001$) when compared to the placebo group. The same trend was observed in the vaginal delivery group with the active treatment showing a significant reduction in VAS ($P=0.022$) and VNS scores ($P=0.005$). The authors also assessed if TENS reduced the need for additional analgesia. There was no difference between the active TENS and placebo group for vaginal delivery ($P=0.83$), but in the cesarean arm the active treatment group had a significant reduction in analgesic need ($P=0.006$).

Acute Pain: Mixed Acute Pain Conditions

A 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). (17) 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.

A systematic review and meta-analysis of TENS for acute pain management in the pre-hospital setting was published in 2013. (47) A literature search identified 4 sham-controlled RCTs of TENS including a total of 128 patients. On pooled analysis of these studies, TENS was superior to sham, with a clinically significant reduction in pain severity and a mean reduction of 38mm on VAS (95% CI: 28-48; P<0.0001). The 4 studies were found to have significant heterogeneity (I2 = 94). The difference in mean final pain score compared to sham treatment was 33mm (95% CI: 21-4; P<0.0001). The authors also found that TENS significantly reduced anxiety when compared to the sham treatment with an overall 26mm lower score on VAS for TENS (95% CI: 17 -35; P<0.0001). No studies reported adverse events for TENS.

Acute Pain: Tennis Elbow

A multicenter randomized controlled trial of TENS as an adjunct to primary care management for tennis elbow was identified. Thirty-eight general practices in the West Midlands, UK recruited 241 adults who had a new or first diagnosis of tennis elbow. (48) Participants were randomized to TENS once per day for 45 minutes over 6 weeks or until resolution of pain plus primary care management (consultation with a general practitioner followed by information and advice on exercise) versus primary care management alone. Both groups saw a large (>25%) within group improvement in pain intensity, with the greatest improvement during the first 6 weeks of treatment. ITT analysis revealed no difference in improvement of pain (-0.33, 95% CI: -0.96 to 0.31; P=0.31) between the two 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 TMS was very poor with only 42 (35%) meeting a prior adherence criteria. Per protocol analyses did show a statistically significant difference in favor of TENS at 12 months (P=0.030) but not during other time periods.

Other

Other: Dementia

Efficacy of TENS for dementia was considered inconclusive in a Cochrane review from 2003. (10)

Other: 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. (49) 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.

A paired-sample randomized cross-over trial of TENS for improving strength, proprioception, and balance was conducted with 29 mobile stroke survivors who had no pre-existing conditions which limited mobility. (50) Participants were given a single session of active TENS plus a session of control sham treatment with each session lasting approximately an hour. The authors found that all participants were able to tolerate the TENS treatment although one participant couldn't feel the active treatment at maximum intensity. Participants improved in forward reach with a mean difference of 4.16cm (P=0.009), velocity with a mean difference of 0.03ms (P=0.002), plantarflexor strength with a mean difference of 4.34 N/m, and JPS plantar flexion with a mean difference of -1.8 degrees (P=0.029). The mean differences for JPS dorsiflexion and dorsiflexor strength did not vary significantly between the TENS and control arms.

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 transcutaneous electrical nerve stimulation (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, the best evidence exists for treatment of chronic, intractable pain, and there is strong clinical support for this indication. The available evidence indicates that TENS can improve chronic intractable pain in some patients, and there is also 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.

For indications other than chronic, intractable pain, the evidence does not permit conclusions on the efficacy of TENS. This includes acute pain, treatment of post-stroke patients, and prevention of migraine headaches. For the prevention of migraine headaches, one small RCT reported a greater proportion of patients achieving at least 50% reduction in migraines with TENS compared to sham placebo, and modest reductions in the number of total headache and migraine days. This manufacturer sponsored trial needs to be corroborated before conclusions can be made on the efficacy of TENS for preventing migraine headaches. Therefore, TENS is considered investigational for all other indications besides chronic, intractable pain.

Practice Guidelines and Position Statements

The European Headache Federation, citing concerns about an ineffective sham procedure for TENS in headache methodology studies and the overall limited level of evidence, recommend that there is insufficient evidence for the use of TENS in headache prophylaxis and to abort an acute headache. (51)

Guidelines from the Osteoarthritis Research Society International (OARSI) 2014 recommend that TENS is not appropriate for the use of multiple-joint osteoarthritis and is of uncertain value in the treatment of knee-only osteoarthritis. (52)

National Comprehensive Cancer Network (NCCN) clinical practice guidelines on adult cancer pain from 2013 indicate that nonpharmacologic interventions including TENS may be considered in conjunction with pharmacologic interventions as needed (Category 2A). (53)

National Cancer Institute (NCI) 2013 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. (54)

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. (55)

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. (56) 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). (57) 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. (58)

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. (59) 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."(60)

The United Kingdom's National Collaborating Centre for Women's and Children's Health and NICE 2008 guidelines on intrapartum care state that there is high-level evidence that TENS is not an effective analgesic in established labor, and there is no high-level evidence on the analgesic effect of TENS in the latent phase of labor. (61) 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. (62) 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. (63) 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. (64) 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. (65) 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

The Centers for Medicare and Medicaid Services (CMS) currently have the following national coverage decisions on TENS (66-70): Reproduction without authorization from Blue Cross and Blue Shield Association is prohibited. Medical Policy Reference Manual

- National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13) (66)

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) (70)

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) (67)

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 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) (68)

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: o 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;

    o 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) (69)

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.

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits.

POLICY TITLE	TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION
POLICY NUMBER	MP-6.020

A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

TOP

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
64550								

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HCPCS Code	Description
E0720-E0731	TENS code range
A4595	Electrical stimulator supplies, 2 leads, per month (e.g., TENS, NMES)
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient.

ICD-9-CM Diagnosis Code*	Description
337.20-337.29	Reflex sympathetic dystrophy
338.21-338.29	Chronic pain
338.4	Chronic pain syndrome

POLICY TITLE	TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION
POLICY NUMBER	MP-6.020

ICD-9-CM Diagnosis Code*	Description
353.0-353.9	Nerve root and plexus disorders
354.0-354.9	Mononeuritis of upper limb and mononeuritis multiplex
355.0-355.79	Mononeuritis of lower limb and unspecified site
356.0-356.9	Hereditary and idiopathic peripheral neuropathy
719.40-719.49	Pain in joint
720.2	Sacroiliitis, not elsewhere classified
721.0-721.91	Spondylosis and allied disorders
722.0	Displacement of cervical intervertebral disc without myelopathy
722.10-722.11	Displacement of thoracic or lumbar intervertebral disc without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.4	Degeneration of cervical intervertebral disc
722.51-722.52	Degeneration of thoracic or lumbar intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.70-722.73	Intervertebral disc disorder with myelopathy
722.90-722.93	Other and unspecified disc disorder
723.0	Spinal stenosis in cervical region
723.1	Cervicalgia
723.2	Cervicocranial syndrome
723.3	Cervicobrachial syndrome (diffuse)
723.4	Brachial neuritis or radiculitis NOS
724.00-724.09	Spinal stenosis, other than cervical
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.6	Disorders if sacrum
724.70-724.79	Disorders of coccyx
724.9	Other unspecified back disorders
729.1	Myalgia and myositis, unspecified
729.2	Neuralgia, neuritis and radiculitis, unspecified
729.5	Pain in limb

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

POLICY TITLE	TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION
POLICY NUMBER	MP-6.020

Transcutaneous Electrical Nerve Stimulation is investigational for treatment of Migraines

ICD-9-CM Diagnosis Code*	Description
346.0	Migraine with aura

The following ICD-10 diagnosis codes will be effective October 1, 2015

ICD-10-CM Diagnosis Code*	Description
G89.21 - G89.8	Chronic pain, not elsewhere classified, code range
G89.4	Chronic pain syndrome
G90.50-G90.59	Complex regional pain syndrome I (CRPS I), code range
M25.50- M25.579	Pain in joint, code range
M54.10- M54.18	Radiculopathy, code range
M54.2	Cervicalgia
M54.30-M54.32	Sciatica, code range
M54.40-M54.42	Lumbago with sciatica, code range
M54.5	Low back pain
M54.6	Pain in thoracic spine
M54.81, M54.89	Other dorsalgia codes
M54.9	Dorsalgia, unspecified
M79.1	Myalgia
M79.2	Neuralgia and neuritis, unspecified
R52	Pain, unspecified

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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X. POLICY HISTORY

TOP

MP-6.020	**CAC 10/25/2011** Adopted BCBSA for TENS, removed TENS information from Electrical Stimulation MP and created this new separate policy. Revised wording and formatting, coverage criteria unchanged.
	CAC 6/4/13 Consensus review, References updated; no changes to the policy statements. FEP variation revised to refer to the FEP policy manual. Administrative code review complete. **Administrative change 7/25/13**- NCD reference update.
	CAC 3/25/14 Consensus. No change to policy statements. References updated. Rationale section added.
	CAC 5/20/14 Minor revision. Policy statement is being revised to indicate the use of TENS in the prevention of migraine headaches is considered investigational. References updated and rationale added. Guidelines which address supply limits added to the policy. Codes reviewed.

Top

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