Name of Policy:
Transcutaneous Electrical Nerve Stimulation (TENS)

Policy #: 375
Category: DME
Latest Review Date: April 2014
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
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, i.e., the patient’s home, a physicians’ office, or in an outpatient clinic.

TENS has been used to treat chronic intractable pain, post-surgical 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 process. Percutaneous electrical nerve stimulation is similar to TENS, but uses micro-needles 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.

**Policy:**
**Effective for dates of services on or after January 1, 2011:**
Transcutaneous electrical nerve stimulation (TENS) units, application of surface neurostimulator and related supplies (e.g. leads, batteries, electrodes, conductive garments, etc) used with TENS devices do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**Effective for dates of service on or after September 24, 2009 through December 31, 2010:**
A 30 day trial of transcutaneous electrical nerve stimulation (TENS) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to establish the efficacy for the management of refractory chronic pain (e.g., chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when all the following conditions have been met:
- The pain is unresponsive to at least three months of conservative medical therapy (e.g. non-steroidal anti-inflammatory medications, ice, rest and/or physical therapy);

**AND**
- The trial period is monitored by a physician
  - The physician’s documentation 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.

**Continued use of transcutaneous electrical nerve stimulation (TENS) meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage 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;
  - Documentation of efficacy should include:
- Perceived intensity of pain with and without TENS (e.g., two point or 30% improvement in Visual Analog Scale (VAS), reduced pain medication, use or reduced use of need for other pain control modalities)
- Ongoing medication requirements for pain relief (if any)
- Other modalities used for pain control (if any)

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
  - Documentation of compliance should include
    - Frequency and duration of application of TENS.

**Use of a form-fitting conductive garment with TENS meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:
- **All** the above coverage criteria for TENS are met;

AND

- 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 must be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires; or
- 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; or
- The patient has a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes, and lead wires.

**Supplies**, including but not limited to leads and batteries, **for use with TENS meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when:
- **Patient is evaluated by ordering physician** for continued efficacy of and compliance with TENS **on an annual basis**;
  - Documentation of efficacy should include
    - Perceived intensity of pain with and without TENS (e.g., two point or 30% improvement in Visual Acuity Scale (VAS)
    - Ongoing medication requirements for pain relief (if any)
    - Other modalities used for pain control (if any)

AND

- **Patient continues to be compliant in the use of TENS**
  - Documentation of compliance should include
    - Frequency and duration of application of TENS.
Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
In 2004, a literature search identified two Cochrane Reviews along with several randomized controlled trials (RCTs) on the use of TENS. The authors of the Cochrane Reviews concluded that the evidence was inadequate to draw conclusions about the effects of TENS. The RCTs were also inadequate in this regard.

A 2007 update examined ten Cochrane Reviews on TENS. Overall, evidence for the efficacy of TENS for different pain conditions was weak. Two Cochrane Reviews concluded that there is limited and inconsistent evidence for the use of TENS as an isolated treatment for low back pain, and that results in patients with rheumatoid arthritis of the hand were conflicting. Efficacy of TENS for neck pain, headache, shoulder pain after stroke, and dementia were considered inconclusive in three other reviews. One Cochrane Review of nine small controlled trials found high frequency TENS to be effective for the treatment of dysmenorrheal. Another review 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.

**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. For the treatment of chronic low back pain, four high-quality RCTs (585 patients) met the selection criteria. There was conflicting evidence about whether TENS reduced back pain, and consistent evidence from two 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. The evidence on TENS for chronic low back pain of various etiologies (some neurologic) included two Class I studies (prospective randomized trial with masked outcome assessment in a representative population) and three Class II studies (randomized trial not meeting Class I criteria or a prospective matched group cohort study in a representative population). The Class I studies compared TENS to TENS-sham with four or six 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 two of the three 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. Seventy-nine patients were randomized to six TENS sessions over three 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 four points with TENS and by one point in the exercise and acetaminophen groups. In the control group, VAS worsened by one 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.

Diabetic Peripheral Neuropathy
The AAN’s 2010 evidence-based review of the efficacy of TENS in the treatment of pain in neurologic disorders identified two Class II studies comparing TENS to sham TENS and one Class III study that compared TENS to high-frequency muscle stimulation for patients with mild diabetic peripheral neuropathy. 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 two 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. In this study, current was applied at an intensity of 30-40 micro-Amps rather than the usual intensity of milliamps, and patients were treated for 30 minutes, three times per week. After four 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 two RCTs (total of 64 participants) met the selection criteria for inclusion in the systematic review. 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. The small sample sizes and differences in patient study populations of the three RCTs prevented meta-analysis. Results on TENS for cancer pain remain inconclusive.
Fibromyalgia
A placebo-controlled cross-over RCT from 2013 investigated the effect of a single treatment of TENS in 41 patients with fibromyalgia. Patients were blindly allocated to either no treatment, active TENS treatment or placebo treatment. Each of the treatment arms had therapy once per week for a three-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. TENS was administered for 20 minutes at 12 hour intervals for seven 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, eight in the single TENS group, and by four patients in the placebo group. Fatigue increased for three patients in the placebo group, but decreased in seven patients in the dual TENS group and five patients in the single TENS group. No adverse events were reported.

Refractory Chronic Pelvic Pain
An observational study of 60 men consecutively treated with TENS for refractory chronic pelvic pain syndrome was published in 2013. 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.

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. An updated Cochrane review from 2009 identified 14 additional trials, resulting in the inclusion of 18 small trials in 813 patients. Eleven trials used TENS, four used interferential current stimulation, one trial used both TENS and interferential current stimulation, and two 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. Included in the review were 11 studies (259 subjects on active therapy) using TENS, acupuncture-like TENS (AL-TENS), or interferential stimulation; nine 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 six studies) on the use of TENS or AL-TENS for osteoarthritis of the knee. The inclusion of two 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. Double-blind assessment during the treatment session found a significant increase in pressure pain threshold at the knee for both low- and high-frequency TENS. There was no effect of TENS on cutaneous mechanical pain threshold, heat pain threshold, or heat temporal summation. All three groups reported a reduction in pain at rest and during the timed up-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. 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 three times a week for four weeks. At two 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 two months post treatment or at three months post treatment. Similarly the TENS group had a greater improvement on the Lequesne index at two 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 three 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 three 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). Investigators and participants were blinded to treatment. Participants were treated for six weeks and directed to use the TENS device as needed for pain relief. 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.

**Rheumatoid Arthritis**
Cochrane reviews from 2002 and 2003 concluded that results in patients with rheumatoid arthritis were conflicting.

**Phantom Limb Pain**
A 2010 Cochrane review found no RCTs on TENS for phantom pain and stump pain following amputation. 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**
A 2013 report by the Cochrane Collaboration reviewed the evidence on TENS for the treatment of chronic neck pain. 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 (seven 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.

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

**Headache**
A 2004 Cochrane review assessed noninvasive physical treatments for chronic/recurrent headache. Twenty-two studies with a total of 2,628 patients (age 12 to 78 years) met the inclusion criteria. The review included five types of headache and various noninvasive treatments including spinal manipulation, electromagnetic fields, and a combination of TENS and electrical neurotransmitter modulation. Combination TENS and electrical neurotransmitter modulation 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. The clinical information on Cefaly was supplied by two studies, the PREvention of Migraine using the STS Cefaly (PREMICE), and a European post-marketing surveillance study. 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 one patient discontinued the trial because of a reported device-caused headache. After a one month run-in period, patients were instructed to use the device daily for a three 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 three 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 respondents (≥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 third 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 four participants (0.2%), reversible forehead skin irritation in five 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%).

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). 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 six 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). The data were converted to a percentage improvement in VAS scores, and 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 two of the included trials (Deyo et al 1990 and Machin et al 1988) 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 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%). 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). The nearly 50% patient satisfaction rating in the sham control group suggests a strong nonspecific effect with this treatment protocol. Survival analysis over the course of one year revealed no significant difference in the percentage of patients who were satisfied with treatment (willing to continue). At one-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).

**Surgical Pain**

In a double-blind study, 40 patients undergoing inguinal herniorrhaphy were randomly assigned to active or placebo TENS for postsurgical pain. 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 two and four 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. 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. On an 11-point numerical scale, pain 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. All patients were treated according to a standard care protocol which postoperatively gave thoracic epidural analgesia infusion of Bupivacaine 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 nine 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.

**Dysmenorrhea**

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

**Labor and Delivery**

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

**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 non-procedure pain (e.g., postpartum uterine contractions and rib fractures). 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. 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 four 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.

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. Participants were randomized to TENS once per day for 45 minutes over six 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 six 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 six weeks, six 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
Dementia
Efficacy of TENS for dementia was considered inconclusive in a Cochrane review from 2003.

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. Although the methodologic quality was considered generally good, only four 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 six-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. 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.
Overall, evidence for the use of transcutaneous electrical nerve stimulation (TENS) from high-quality trials remains inconclusive. The available studies are not consistent on whether TENS improves outcomes, and the overall strength of the evidence is weak for all indications.

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.

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.

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.

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).

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.

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.

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. 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 two Class I studies), and that TENS should be considered for the treatment of painful diabetic neuropathy (Level B, probably effective, based on two Class II studies).

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. 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 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. 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 neuro-stimulation, 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 non-menstrual pelvic pain. 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. No recommendations for TENS were made; the panel concluded that TENS had not been proven effective for chronic low back pain.

**Key Words:**
Transcutaneous electrical nerve stimulation, TENS, Flex-IT/Flex-Gar, Cefaly (STX-med, Herstal Belgium)

**Approved by Governing Bodies:**
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.

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.

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this
policy when applicable.

Effective for dates of service on or after July 1, 2010:
Transcutaneous electrical nerve stimulation (TENS) units, application of surface neurostimulator
and related supplies (e.g. leads, batteries, electrodes, conductive garments, etc) used with TENS
devices will not be a covered benefit for some groups. Coverage for these items/services should
be verified.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.

Coding:
CPT Codes: 64550 Application of surface (transcutaneous) neurostimulator

HCPCS Codes:
A4595 Electrical stimulator supplies, 2 leads per month (e.g., TENS, NMES)
A4630 Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
E0720 Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation
E0730 Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for multiple nerve stimulation
E0731 Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient’s skin by layers of fabric)

References:
1. American Congress of Obstetricians and Gynecologists (ACOG). ACOG Practice
2. Bjersa K, Andersson T. High frequency TENS as a complement for pain relief in
postoperative transition from epidural to general analgesia after pancreatic resection.


Policy History:
Medial Policy Group, September 1999
Medical Policy Group, June 2003
Medial Policy Group, August 2008
Medical Policy Panel, July 2009
Medical Policy Group, July 2009 (2)
Medical Policy Administration Committee, August 2009
Available for comment August 10-September 23, 2009
Medical Policy Group, January 2010 (2)
This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plans contracts.