

Policy #: 003

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Title

TENS and PENS/PNT

Description

Transcutaneous electrical nerve stimulator (TENS) is an electronic device that applies electrical stimulation to the surface of the skin at the site of pain and is designed to relieve chronic intractable pain, post-surgical pain, and pain associated with active or post-trauma injury unresponsive to other standard pain therapies. In addition to potential blockade of local pain pathways, it has been proposed that TENS may provide pain relief through release of endorphins (substances that are produced by the body that bind to receptors in the central nervous system that relieve pain).

TENS consists 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 by the FDA. Approval of these devices does not require data regarding clinical efficacy.

Percutaneous electrical nerve stimulation (PENS) is similar in concept to transcutaneous electrical nerve stimulation but differs in that needles are inserted either around or immediately adjacent to the nerve serving the painful area and then stimulated. PENS is believed to improve blood flow to the affected area. PENS is generally reserved for patients who fail to get pain relief from TENS, apparently due to obvious physical barriers to the conduction of the electrical stimulation (e.g., scar tissue, obesity). PENS must be distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. In PENS the location of stimulation is determined by proximity to the pain rather than the theories of energy flow that guide placement of stimulation for acupuncture. As with TENS there are a number of FDA approved devices.

Percutaneous neuromodulation therapy™ (PNT) is a variant of PENS in which fine filament electrodes are temporarily placed at specific anatomical landmarks in the back. Treatment regimens consist of 30- minute sessions, once or twice a week for 8 to 10 sessions.

Functional neuromuscular stimulation (FNS) attempts to replace stimuli from destroyed nerve pathways with sequential electrical stimulation of muscles in spinal cord injured patients. The goals of FNS in this population are to stand or walk independently or to maintain healthy muscle tone and strength. In general, only patients with injuries in the mid-back region (spinal column bones T4 to T12) are considered candidates. Injuries in the upper back (T1–T3) are associated with poor trunk stability, while lumbar (lower back) lesions imply lower extremity nerve damage which would not respond to FNS. FNS technologies differ in how the electrodes are placed, either implanted, placed transcutaneously, or percutaneously. Functional neuromuscular stimulation is also used for gait training in post-stroke patients unable to restore normal gait with conventional physical therapy.

When services are covered for all Products including Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS Plus Rx

We cover **TENS and PENS/PNT** for **Medicare HMO Blue and Medicare PPO Blue** members only, in accordance with CMS regulations^{4, 33, 37}

We cover **neuromuscular electrical stimulators (NMES) for disuse atrophy** for **Medicare HMO Blue and Medicare PPO Blue** members, **only**, in accordance with CMS regulations, even though there is not enough scientific evidence to make conclusions about health outcomes compared to other forms of treatment.^{13,14}

We cover **neuromuscular electrical stimulators (NMES)/ functional electrical stimulators (FES) for Medicare HMO Blue and Medicare PPO Blue and Medicare PFFS PlusRx** members, **only**, in accordance with CMS regulations, for walking in spinal cord injury (SCI) patients with **all** of the following characteristics:³⁵

- persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve)³⁵
- persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently³⁵
- persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction³⁵
- persons that possess high motivation, commitment and cognitive ability to use such devices for walking³⁵
- persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes³⁵
- persons that can demonstrate hand and finger function to manipulate controls³⁵
- persons with at least 6-month post recovery spinal cord injury and restorative surgery³⁵
- persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis³⁵
- persons who have demonstrated a willingness to use the device long-term.³⁵

When services are not covered for all Products including Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS Plus Rx

We do not cover **TENS or PENS/PNT (except for Medicare HMO Blue and Medicare PPO Blue members, as noted above)** because these treatments are considered *investigational* and do not meet the BCBSMA Medical Technology Assessment Guidelines, #350. This includes but is not limited to the following clinical conditions.^{7-11,14, 32, 37}

- Chronic back pain^{1, 32}
- Pain associated with childbirth (i.e. pain of labor and vaginal delivery.)^{2, 32}
- Chronic pain^{3, 32}
- Post-surgical pain.^{3,10, 32}
- Dementia³²
- Rheumatoid arthritis¹

We do not cover **neuromuscular electrical stimulators (NMES), except for Medicare HMO Blue and Medicare PPO Blue** members, because there is not enough scientific evidence to conclude about health outcomes compared to other forms of treatment.^{14,31,36}

We do not cover **neuromuscular electrical stimulators (NMES) /functional electrical stimulators (FES) for Medicare HMO Blue and Medicare PPO Blue (except as noted above)**, for walking in spinal cord injury (SCI) patients with **any** of the following:³⁵

- persons with cardiac pacemakers³⁵
- severe scoliosis or severe osteoporosis³⁵
- skin disease or cancer at area of stimulation³⁵

- irreversible contracture³⁵
- autonomic dysreflexia.³⁵

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. While data on vagal nerve stimulations have been largely or predominantly in patients with partial onset seizures, patients with generalized seizures may also be considered.²¹ For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed

Blue Cross Blue Shield of Massachusetts
 Provider Appeals
 PO Box 986065
 Boston, MA 02298

Prior to performance of service

Blue Cross Blue Shield of Massachusetts
 Case Creation/Medical Policy
 One Enterprise Drive
 Quincy, MA 02171
 Tel: 1-800-327-6716
 Fax: 1-888-641-5330

Managed care guidelines

- **TENS, PENS/PNT, and NMES for Medicare HMO Blue members:** referrals are not required, however, the device must be medically necessary, prescribed by a plan physician and provided by a network provider.
- Any specialist visit requires a referral for **Medicare HMO Blue**
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorizations are not required.
- Authorization for inpatient admission is required.

Indemnity and PPO guidelines

All authorization requirements are determined by the individual's subscriber certificate, however:

- Authorizations are required for all inpatient services
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate
- Referrals to a specialist are not required.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

TENS / PENS/PNT / NMES

- CPT code 64550, application of surface (transcutaneous) neurostimulator
- CPT code 64560, percutaneous implantation of neuromuscular electrodes; autonomic nerve.
- CPT code 64565, percutaneous implantation of neuromuscular electrodes; neuromuscular
- CPT code 64577, incision for implantation of neurostimulator electrodes; autonomic nerve

- CPT code 64580, incision for implantation of neurostimulator electrodes; neuromuscular
- HCPCS Level II code K0600, functional neuromuscular stimulator, transcutaneous stimulation of muscles of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program. (**Non-covered effective 4/1/03**) (*Deleted code effective 1/1/06*)

NOTE: CPT code 64999 would be used to code for PENS and PNT.

CPT codes for percutaneous implantation of neurostimulator electrodes (i.e. 64553-64565) are not appropriate since PENS and PNT use percutaneously inserted needles and wires rather than percutaneously implanted electrodes.

The stimulation devices used in PENS and PNT are not implanted therefore CPT code 64590 is also not appropriate.

- HCPCS Level II code E0720, TENS, two lead, localized stimulation
- HCPCS Level II code E0730, TENS, four or more leads, for multiple nerve stimulation
- HCPCS Level II code E0731, form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)
- HCPCS Level II code E0745, neuromuscular stimulator, electronic shock unit.
- HCPCS Level II code E0770, functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (*New code effective 1/1/09*)
- HCPCS Level II code A4595, electrical stimulator supplies, 2 lead, per month, (e.g. TENS, NMES)
- HCPCS Level II code A4630, replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient-
- HCPCS Level II code L8680, Implantable neurostimulator electrode, each (*New code effective 1/1/06*)

Modifiers:

- modifier RR (rental)
- modifier NU (purchase)

Other information

TENS/PENS

- Neuromuscular stimulator for scoliosis (E0744) is not a covered item based on the Medical Technology Assessment Guidelines, (#350).
- Transcutaneous Electronic Nerve Stimulator (TENS), and Percutaneous Electronic Nerve Stimulator (PENS), when covered, are a DME benefit and are subject to any applicable DME co-insurance and benefit maximum.
- We do not reimburse separately for electrodes (A4556), lead wires (A4557), conductive paste, or replacement of batteries (A4630).

For Medical Technology Assessment Guidelines refer to (#350)

For the Medical Technology Assessment Guidelines Non-Covered list refer to #400

Policy update history

TENS/PENS policy Issued 1/15/88. Revised 3/31/91 to exclude low back pain. Reviewed 4/97 after a literature review; no changes were made to coverage. Revised 6/96 to exclude coverage except for Medicare HMO Blue patients, in accordance with CMS regulations (DMERC). Reviewed 4/97 after a literature review; no changes were made to coverage. Revised 8/97 to include coverage for neuromuscular stimulators for disuse atrophy for Medicare HMO Blue (effective 1/1/98), in accordance with CMS regulations (reference: CIM 35-77). Updated 12/98 to include authorization information for managed care plans. Updated 8/99 to include billing information for ICD-9-CM procedure codes 04.92-04.93. Updated 8/02 to clarify coverage exclusion for neuromuscular stimulations except for Medicare HMO Blue members, in accordance with Medicare guidelines. Reviewed 1/03 MPG Neurology, no changes in coverage were made. Updated 6/03 to clarify coverage exclusion for functional neuromuscular stimulator except for Medicare HMO Blue members, in

accordance with Medicare guidelines. Reviewed 7/03 MPG orthopedic, no changes in coverage were made. Reviewed 1/04 MPG neurology, no changes were made. Reviewed 2/04 MPG Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Reviewed 7/04 MPG Orthopedic, no changes in coverage were made. Updated 2/05 to include references and rationale from BCBSA National Policy on functional neuromuscular stimulation to provide ambulation. 2/05 MPG Psychiatry, ophthalmology and endocrinology, no changes in coverage were made. 5/05 clarification made to document bringing non-coverage information pertaining to PENS noted under foot notes to 'when services are no covered' for Plans other than Medicare HMO Blue and Medicare PPO Blue, references added to foot note #37 from BCBSA national medical policy supporting non-coverage for PENS like modality-percutaneous neuromodulation therapy (PNT), CMS web links updated in foot notes # 4, 13, 14, 34, 35. Updated 9/05 based on review of 2005 BCBSA National policy without change in policy statement specific to functional neuromuscular stimulation to provide ambulation. Updated 1/06 after review 9/05 based on National Policy 7.01.63-Deep Brain Stimulation to include coverage for Primary Dystonia and to exclude coverage for cluster headaches and for other movement disorders, including but not limited to multiple sclerosis and post-traumatic dyskinesia; effective 2/06; individual consideration for multiple sclerosis was deleted; references added. Reviewed 7/05 MPG-Orthopedic, no changes in coverage were made. Updated 1/06 after review 9/05 based on BCBSA national policy specific to vagal nerve stimulation to clarify non coverage of depression as well as coverage exclusion of VNS for treatment of headaches and essential tremors, effective 2/06. Reviewed 1/06 MPG-Neurology, no changes in coverage were made. 6/06 Footnote #38 (re: Deep Brain Stimulation) edited to include coverage/non-coverage rationale and updated literature from the BCBSA medical policy (issue 1:2006). Reviewed 7/06 MPG - Orthopedic/Rheumatology, no changes in coverage were made. 10/06 update information: 1. policy comparison review of National Policy # 7.01.29 conducted; no changes in coverage were noted. 2. June 2006, policy comparison review of National Policy # 7.01.63 *Deep Brain Stimulation*- references added, footnote #38. Updated 12/06 after review of BCBSA policy addressing vagal nerve stimulation without change in policy statements under footnote 39. Updated 12/06 to remove policy exclusion statement and IC policy guideline on vagal nerve stimulation for depression from this policy and separately address it under Behavioral Health policy #038. Reviewed 1/07 MPG Neurology, no changes in coverage were made. Reviewed 2/07 MPG Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. 4/07 Comparison review of BCBSA policy 7.01.25 completed, BCBSMA covered and non-covered statements for spinal cord stimulation clarified; and footnote 40 developed to include BCBSA policy rationale, literature review, and references. Comparison review of BCBSA policy 7.02.09 completed, no change in policy statement; and footnote #32 in the BCBSMA medical policy expanded upon to reflect BCBSA national policy rationale, review of references, and updated reference list. Reviewed 7/07 MPG Neurology, no changes in coverage were made. 2/08, Comparison review of BCBSA policy 8.03.01 completed, no change in policy statement, references added. 2/08, Comparison review of BCBSA 1.01.27 completed, non-coverage for rheumatoid arthritis status added. Reviewed 1/08 MPG-Neurology, no changes in coverage were made. Updated during review of BCBSA #1.01.09 to add references 18-20 and 22-26. Policy remains unchanged. Updated 7/08 based on BCBSA policy # 7.01.29, policy updated with literature review; reference number 13 added; policy statement unchanged. Updated 7/08 based on BCBSA policy # 1.01.09, with literature review; older rationale updates condensed; references reordered and reference numbers 18–20, 22-26 added; policy statements revised to differentiate acute and chronic pain conditions; remains investigational. Updated 11/08 to be stand alone policy under title TENS, PENS, PNT. Reviewed 1/09 MPG – Neurology and Neurosurgery, no changes in coverage were made. Updated 10/09 to clarify Code Information by adding HCPCS code E0770 and the link to the CMS NCD listed in footnote 35 was refreshed.

Footnotes and References

¹ **Back pain:** New England Journal of Medicine June 7, 1990, 322(23):1627-34, Deyo, et al., evaluating treatments for chronic back pain. TENS, stretching exercises, and both were considered. Patients with chronic back pain (median 4.1 years duration) were randomized to daily TENS (n=36), sham TENS (36) or TENS plus exercise (37), or sham TENS plus exercise (36). One month later, there were no differences noted with TENS on the 11 indicators studied, including pain, function, and back flexion. However, those in the exercise groups had significant improvement in pain and activity scores. Two months after the intervention period, most patients had discontinued their exercises, and the improvements seen initially were not maintained. Also see

JAMA 1983; 250:1057-62 Conservative Therapy for Low Back Pain: *Distinguishing Useful from Useless Therapy*. The randomized trial of Thorsteinsson et al. *The placebo effect of transcutaneous electrical stimulation* published in Pain 1978; 5:31-41, though data was not completely reported, did serve to demonstrate the large placebo effect (32%) of non-functioning TENS units. All 11 studies of TENS were considered too methodologically imperfect to assess health outcomes in patients with low back pain.

² Blue Cross Blue Shield Association's TEC (Technology Evaluation Center) 1988 assessment of TENS for acute post-op pain, labor and delivery, and chronic pain.

Labor and delivery: Two major studies were evaluated. Harrison (1986): no differences were found between active TENS and placebo TENS with respect to analgesia/ anesthesia. Active TENS users noted subjective responses of success. Grim and Morey (1985) turned TENS units on and off, allowing the patients to serve as their own controls. Outcome was rated by questionnaire 24 hours later. 87% reported some degree of pain relief. Therefore, the two available studies were not in agreement. Theoretically, for the TENS unit to relieve pain, the nerve fibers must be located in between the two electrodes on the TENS unit. During L & D, pain arises from multiple sources, unlikely to fall between the TENS electrodes.

³ Based upon the 5/96 TEC (Technology Evaluation Center) analysis of medical literature from 1/90-2/96 on TENS or PENS for chronic or post-op pain management compared to other modalities, depending on body area, including medications, splints, exercise, and others. Studies generally used visual analog scales or the McGill Pain Questionnaire. Other outcomes included changes in functional status and movement. Note that acute situational pain (the pain of a blood draw or other procedure) was not addressed in this assessment. Except in one case, only randomized trials were included. Solomon (1980) was included because of its large sample size (n=196). A study by VanderArk (1975) was not used because they failed to include statistical analyses of results.

Chronic Pain: Only 1 of four recent studies analyzed showed significant benefit of TENS relative to control: Guieu (1991). However, this result was only obtained when TENS was combined with vibration: TENS alone was no better than sham controls. In other studies, TENS was significantly inferior to alternative treatments. Exercise was found to reduce pain relative to TENS in 3 studies, including one by Deyo (1990). In another study, splints outperformed TENS for patients with TMJ dysfunction.

Post-operative Pain: Blue Cross Blue Shield Association's TEC (Technology Evaluation Center) 1988 assessment of TENS for acute post-op pain, labor and delivery, and chronic pain. In a TENS was studied post orthopedic, cardiac, abdominal, thoracic, C-section, and amputation procedures. Comparisons were made to placebo-TENS, aspirin and narcotics. Active TENS resulted in significant pain relief in over half of patients. There was decreased need for medication, reduced hospital days, diminished subjective reports of pain, and improvements in function. However, many patients who experienced significant pain relief with active TENS also received significant relief with placebo-TENS. Conn (1986) found no difference in patient-reported pain severity between active and placebo-TENS post-appendectomy, yet both groups received more relief than a control group who received analgesics instead.

For the 5/96 TEC assessment, of the 11 studies reviewed, 4 reported that TENS has no treatment effect; furthermore, TENS had no placebo effect. In 2 of these 4, TENS and sham-TENS were compared to no treatment (Walker 1991, Forster 1994). Laitinen and Nuutinen (1991) compared TENS to placebo, and Solomon compared TENS to no treatment. Ledergerber (1978) found no difference between TENS and sham-TENS for relief of post-op pain, but did not test for a placebo effect. Two studies did suggest that TENS might work through a placebo effect (Taylor, 1983, and Conn, 1986). In both, there was no difference between sham and active TENS, but both reduced pain compared to no treatment. Other studies had contradictory findings or serious methodologic flaws. There is not one carefully controlled study of TENS that consistently supports efficacy of use in post-op pain.

PENS: There are no published clinical controlled or uncontrolled studies on PENS, so it is impossible to draw conclusions about health outcomes.

⁴ Based on CMS Coverage Issues Manual, 35-46: http://www.cms.hhs.gov/manuals/06_cim/ci35.asp#_1_51

⁷ *Manipulation of TENS variables has no effect on 2 models of experimental pain in humans.* Foster NE et al in Clin J Pain 1996 Dec;12(4):310-10. The submaximal Effort Tourniquet Technique and cold-pressor pain were evaluated in 32 health subjects. Control, placebo, and 2 TENS settings were evaluated. The Visual Analogue Scale (VAS) and the McGill Pain Questionnaire (MPQ) revealed no significant differences between any of the groups. Various hypothetical explanations are offered.

⁸ *Lack of effect of TENS in experimentally induced delayed onset muscle soreness in humans.* Craig JA et al. Pain 1996 Oct;67(2-3):258-9. 48 subjects were studied 72 hours after induced muscle soreness. Control, placebo, low TENS (200 microseconds, 4 Hz) or high TENS (200 microseconds 110 Hz) were evaluated. Mechanical Pain Threshold/tenderness (algometer), Visual Analog Scales, and the McGill Pain Questionnaire on the third day showed inconsistent effects on a few scores. No significant effects were found for most variables.

⁹ *Outcome of 6-week treatment with TENS compared with splint on symptomatic TMJ disk displacement without reduction.* Linde et al. Acta Odontol Scand 1995 Apr;53(2):92-8. 31 patients were evaluated with flat occlusal splints (24 hr/day) or TENS (90 Hz, 30 min, 3x day). Visual analog scales, and an electronic pocket-sized recorded (Pain-Track) was evaluated. VAS scores showed 1/2 of splint patients were pain-free, or 50% improved at rest and with jaw function. Only 6% of the TENS group experienced these results. Regarding chewing pain, VAS scores improved in 2/3 of splint patients, but only 50% of TENS patients.

¹⁰ *Effect of TENS on pain, medications, and pulmonary function following coronary artery bypass graft surgery.* Forster EL et al. Chest 1994 Nov;106(5):1343-8. This prospective, randomized controlled trial (n=45) assigned patients to TENS, placebo TENS, or control (n=15 each), post-extubation up to 72 hours post op. Outcomes measures included cough, narcotic use, FVC, FEV₁, and PEFr. There were no differences between groups. Pain at rest was significant at p<0.04, but there were no significant differences between TENS and placebo, or between TENS and control groups. Authors concluded that TENS in the immediate post-op period may not be advantageous in pain management or optimization of pulmonary function for CABG patients.

¹¹ *A randomized controlled trial of TENS (CODETRON) to determine its benefits in a rehabilitation program for acute occupational low back pain.* Herman E et al. Spine 1994 Mar1;19(5):561-8. 58 work-injured patients (LBP 3-10 weeks duration) were randomized to standard exercise + placebo stimulation vs. standard exercise + TENS. Outcomes measures included disability, pain, and return to work. No significant differences were noted between groups on any outcome. Exercise alone, continued for 4 weeks, significantly reduced disability and pain scores. No added benefits were noted with the addition of TENS.

¹³ Based upon CMS Coverage Issues Manual 35-77, **neuromuscular electrical stimulation** for disuse atrophy. For additional information see CIM 35-77 at the following website address:
http://www.cms.hhs.gov/manuals/06_cim/ci35.asp

¹⁴ Medicare policy is developed separately from BCBSMA policy. While BCBSMA policy is based upon scientific evidence, Medicare policy incorporates scientific evidence with local expert opinion, and governmental regulations from CMS (Centers for Medicare and Medicaid Services) and the US Congress. While BCBSMA and Medicare policies may differ, our Medicare HMO Blue patients must be offered the same services as Medicare offers. In many instances, BCBSMA policies offer more benefits than does Medicare policy.

For Medicare's policy on **transcutaneous electrical nerve stimulators**, see Coverage Issues Manual 60-20 at the following website address: http://www.cms.hhs.gov/manuals/06_cim/ci60.asp#_60_20, and http://www.cms.hhs.gov/manuals/06_cim/ci35.asp#_1_51

³¹ Based on the Blue Cross Blue Shield Association National policy 8.03.01, *Functional Neuromuscular Stimulation to Provide Ambulation* (issued 4/30/00)

The National policy notes that physiologic outcomes such as conditioning, oxygen uptake, etc. are intermediate short-term outcomes and it is not known whether similar or improved results could be achieved with other training methods. In addition, the results are reported for mean peak values, which may or may not be a consistent result over time. The effect of the Parastep on physical self-concept and depression are secondary outcomes and similar to the physiologic outcomes; interpretation is limited due to lack of comparison with other forms of training. The National policy also noted that all evaluations of the Parastep device were performed immediately following initial training. There are no data regarding whether patients remain compliant and committed with long-term use.

³² Based on the Blue Cross Blue Shield Association National policy 1.01.09., *Transcutaneous Electrical Nerve Stimulator (TENS)*

2006-2007 Update A search of the MEDLINE database for the period of April 2005 through December 2006 identified a number of publications on the use of TENS for acute and chronic pain syndromes. TENS continues to be an active and controversial topic of research.

One recent double-blind randomized study compared 10 days of TENS with sham TENS on pain intensity and willingness to continue treatment in 163 patients with chronic pain of various etiologies. (18) More patients were willing to continue treatment in the TENS group (58%) than in the sham TENS group (42.7%). Although pain intensity was significantly reduced over time for both groups, there was no difference in subjective pain scores between patients treated with TENS or sham controls. The authors noted that this discrepancy may be due to the fixed reporting time for the daily visual analog score (VAS), which might not reflect the patient's experience during the treatment period. The significant improvement in the chronic-pain control group suggests a large placebo component for this treatment.

Several recent randomized studies suggest that TENS may alleviate acute pain. For example, 1 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). (19) Additional studies confirming these results are needed.

Eleven different Cochrane reviews have evaluated TENS over the past 6 years. One review found TENS and acupuncture like TENS to be effective for the treatment of knee osteoarthritis based on 7 mixed quality controlled trials; treatment duration (greater than 4 weeks) was found to be critical. (20) Another review of 9 small controlled trials concluded that high frequency TENS is effective for the treatment of dysmenorrhea. (21) Other Cochrane updates have 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 are conflicting. (22, 23) Efficacy of TENS for chronic pain, neck pain, headache, shoulder pain after stroke, and dementia were considered inconclusive in 4 other Cochrane reviews.

Results on the efficacy of TENS are mixed. This may be due to the wide variety of pain syndromes and treatment methods being examined. Two new systematic Cochrane reviews have been initiated to assess the use of TENS for cancer pain and acute pain. One of these will assess factors that may influence efficacy, such as the type of pain, the type of TENS used, duration of treatment, and whether the study measures acute or chronic outcomes.

Policy Rationale

This policy was originally based on a 1996 TEC Assessment of TENS for the treatment of chronic and postoperative pain. (1) The 1996 TEC Assessment found that the evidence did not clearly show that the effects of TENS exceeded placebo effects.

The following study selection criteria were used in the 1996 TEC Assessment:

- the study contained original empirical data;
- the study design included a TENS treatment group and a control group;
- the study reported on a health outcome relevant to the pain condition treated; and
- the study used a random assignment, control group design.

An updated literature search in October 2002 identified several Cochrane Reviews of TENS. The most comprehensive Cochrane Review was completed by Carroll et al (2), which was last amended in June 2000. It addressed chronic pain due to a variety of conditions. Reviewers searched 5 electronic databases, seeking randomized controlled comparisons of TENS, no treatment, alternative methods of TENS, and sham TENS. Reviewers found 107 reports that were considered for inclusion in the Cochrane Review. A total of 19 randomized trials were judged as meeting study selection criteria. Reports were excluded if the studies:

- were not randomized comparisons of active conventional TENS and sham TENS;
- used flawed methods of randomization;
- did not directly compare 2 forms of conventional TENS, such as low-frequency TENS and high-frequency TENS;
- described TENS used in combination with other analgesic treatments;
- were an unconventional form of TENS;
- did not use subjective pain outcomes;
- were not chronic pain of more than 3 months' duration;
- were abstracts, or letters (i.e., not full journal publication); and
- duplicate publications of published research.

The included studies varied considerably in design, outcome measures, chronic pain conditions, TENS methods, and study quality. Most studies selected small patient samples. Reporting and study methods were generally poor. Adequate blinding was not rated as having been achieved in any of the studies. Variable methods of TENS were used, at various sites, and for different durations. Due to heterogeneity of methods and inability to extract sufficient dichotomous pain outcomes data, it was concluded that meta-analysis was not possible.

Half of the included studies addressed single applications of TENS. The reviewers made the critical observation that such a design fails to address the long-term use and effectiveness of TENS for chronic pain. Most of the reviewed studies do not address how TENS is intended to be used in actual patient care. Of 15 studies that compared single applications of active TENS with inactive control treatment, 10 found an effect favoring active TENS. However, of 7 studies that addressed multiple applications of TENS, only 3 found results favoring active TENS or inactive treatment. Carroll et al summarized by stating that the evidence on use of TENS for chronic pain is inconclusive. They noted that trials do not indicate which stimulation parameters are responsible for any pain relief and that the crucial question of long-term effectiveness has been inadequately addressed. (2)

In the 2002 update, a search of the literature aimed at identifying articles published since the last update of the Cochrane Review by Carroll et al found an article on TENS for knee osteoarthritis by Yurtkuran and Kocagil. (3) While this study found that TENS achieved better pain relief than placebo, it did not address long-term effectiveness, and it is unclear whether the study was adequately blinded.

In addition to the comprehensive Cochrane Review of TENS for chronic pain (2), the Cochrane Library also contains 5 other Cochrane Reviews of TENS for specific pain conditions. Cochrane Reviews by the following reviewers agreed with Carroll et al: Milne et al (4) on chronic low back pain; Pelland et al (5) on rheumatoid arthritis; and Price and Pandyan (6) on post-stroke shoulder pain. Cochrane Reviews on knee osteoarthritis by Osiri et al (7) and primary dysmenorrhea by Proctor et al (8) concluded that a small number of studies for each condition shows TENS to be more effective than sham TENS. Both of these reviews fail to address the key issue of long-term effectiveness and thoroughly examine the potential influence of study quality, thus the Cochrane Review by Carroll et al should be viewed as most relevant.

The 1996 TEC Assessment addressed both chronic pain and postoperative pain. While the Cochrane Review by Carroll et al focused on chronic pain, no Cochrane Review on TENS has targeted postoperative pain. In 2002, a literature search for studies published since 1996 identified 1 randomized trial comparing active TENS with sham TENS among patients undergoing lower abdominal gynecologic surgery (9). The authors found that 3 different TENS techniques reduced the need for postoperative opioids, compared with sham TENS. The report does not clearly state whether patients or investigators were adequately blinded, nor does it mention whether patients withdrew from the study and how any withdrawals were handled in the data analysis. Given these flaws, the recent evidence does not alter the conclusions of the 1996 TEC Assessment.

In a 2004 literature review update, 2 additional Cochrane Reviews (10, 11) were identified along with several randomized controlled trials (RCTs) on the use of TENS (12-17). Neither of the Cochrane Reviews nor any of the RCTs identified were sufficient to alter the conclusions reached above. In the Cochrane Review of TENS for the treatment of rheumatoid arthritis of the hand, Brosseau and colleagues found conflicting results and determined that further study is still needed. (10) In the other Cochrane Review, Cameron and colleagues reviewed the use of TENS for treatment of dementia. (11) The authors concluded that the evidence was inadequate to draw conclusions about the effects of TENS on dementia.

Professional/Scientific Organization Positions

According to the Agency for Healthcare Research and Quality (AHRQ) Guidelines Clearinghouse, the Department of Veterans Affairs published a guideline on management of low back pain or sciatica in the primary care setting. The report stated that “Evidence is insufficient to recommend transcutaneous electrical nerve stimulation (TENS) in the treatment of patients with acute low back pain.”

The American Geriatrics Society produced a guideline in 1998, stating that “... transcutaneous nerve stimulation may be helpful for some patients, but they are expensive and have not been shown to have greater benefit than placebo controls in the management of chronic pain.”

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, transcutaneous electrical nerve stimulation 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 1 RCT and general agreement that TENS is acceptable.

The AHRQ Guidelines Clearinghouse also lists several other guidelines that indicate TENS may be used for management of pain. However, none of these guidelines lists TENS as a major recommendation.

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³³ Based upon the 4/02 Blue Cross Blue Shield Association national policy 7.01.09 including literature review from January 1996 through August 2002. According to BCBSA, evaluation of the recent studies showed that

evidence is still inadequate to reach conclusions about the effectiveness of PENS for the treatment of chronic pain.

³⁴ Based upon the Centers for Medicare and Medicaid Services regulations, Coverage Issues Manual-reference 60-19. For additional information see http://www.cms.hhs.gov/manuals/06_cim/ci60.asp

³⁵ Based upon the Centers for Medicare and Medicaid Services NCD # 160.12, Neuromuscular Electrical Stimulaton (NMES)
http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=160.12&ncd_version=2&basket=ncd%3A160%2E12%3A2%3ANeuromuscular+Electrical+Stimulaton+%28NMES%29

³⁶ Based on Blue Cross Blue Shield Association National policy 8.03.01 (issued 2/04.)
A search of the literature was performed in the MEDLINE database for the period of 2000 to November 2003. No published data were identified that would alter the above conclusion; therefore the policy statement is unchanged. Brissot and colleagues reported independent ambulation was achieved in 13 of 15 patients, with 2 patients withdrawing from the study. (8) In the home setting, 5 of the 13 patients continued using the device for physical fitness, but none used it for ambulation. Sykes and colleagues found low use of a reciprocating gait orthosis device (RGOs) with or without stimulation over an 18-month period. (9) In addition, the more recent Davis study of a surgically implanted neuroprosthesis for standing and transfers after spinal cord injury showed mixed usability/preference scale results for ambulation with device assistance versus conventional transfers in 12 patients followed up for a 12-month period post-discharge. (10) Therefore, the advantage of using device assistance could not be evaluated. Based on Blue Cross Blue Shield National policy 8.03.01 issued 6/27/05. A literature review update for the period November 2003 through 2005; no new clinical trials found. Policy statement is unchanged.

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2006 Update

Based on Blue Cross Blue Shield National policy 7.01.20 issued 10/06. The policy was updated with June 2006 TEC Assessment (treatment-resistant depression) and literature review for other indications; policy statement is unchanged.

Review of the literature for the period of June 2005 through July 2006 did not locate any studies which would alter the conclusions or policy statements for use of VNS for other indications.

Medicare coverage policy notes that “Clinical evidence has shown that vagus nerve stimulation is safe and effective treatment for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. Vagus nerve stimulation is not covered for patients with other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.”

NOTE: Refer to Medical Policy #38 for references/rationale of BCBSA national policy 7.01.20 specific to VNS for treatment resistant depression.

This policy was originally based on a 1996 TEC Assessment of PENS for the treatment of chronic pain. (1) The objective of the 1996 Assessment was to determine if the effects of PENS exceed placebo effects. No clinical studies of PENS were identified by the 1996 Assessment, thus no conclusions about effectiveness could be reached. Subsequently, the policy was updated with a literature search covering the period between January 1996 and February 2004. This 2004 review showed that evidence is still inadequate to reach conclusions about the effectiveness of PENS for the treatment of chronic pain.

The following study selection criteria were used in the 1996 TEC Assessment and the 2004 update:

- the study contained original empirical data;
- the study design included a treatment group and a control group;
- the study reported on a health outcome relevant to the pain condition treated; and
- the study used a random assignment, control group design.

The literature search revealed 8 randomized trials meeting the above criteria. Of the 8, a total of 5 addressed use of PENS in treating chronic back pain. (2-6) A single study focused on each of these conditions: chronic neck pain (7), chronic diabetic neuropathy (8), and chronic headache. (9) All were designed as randomized crossover studies in which sham PENS was compared with between 1 and 3 types of active PENS, in addition to alternative treatments such as TENS or exercise therapy. Patients would undertake 30-minute treatment sessions, 3 times per week for 2 or 3 weeks. The order of treatments was random. On completing a treatment, a 1-week washout period would follow, then the patient would proceed to another treatment until all patients had received all treatments. Post-treatment outcome was assessed either immediately after completing the last session of a treatment or up to 3 days later. All 8 studies were conducted at 1 institution, the University of Texas Southwestern Medical Center in Dallas.

Chronic Low Back Pain

Chronic low back pain in these 5 studies was defined as persisting for a minimum of either 3 or 6 months. All 5 studies were described as single blinded, and 2 specified that they were investigator blinded. (2, 6) However, the reports provide insufficient details to make clear how investigators achieved blinding or whether such methods of blinding were effective. None of the reports state whether subjects withdrew from the study before

its completion. Ghoname et al (2) compared sham PENS, active PENS, and TENS in 64 patients. Active PENS achieved better outcomes than sham PENS on visual analog scale (VAS) pain scores, and daily oral analgesic requirement. Active PENS was better than sham PENS and TENS on physical activity, quality of sleep, and preference. Ghoname et al (3) administered sham PENS, active PENS, TENS, and exercise therapy in 60 patients. Active PENS resulted in better outcomes than all other modalities in terms of VAS pain, analgesic requirements, physical activity, quality of sleep, and preference.

Hamza et al (4) varied the duration of active electrical stimulation at 3 levels (15, 30, and 45 minutes) and compared them with sham stimulation in 75 patients. These investigators confirmed that sham PENS had the least effect, and results were best when the stimulation lasted 30 or 45 minutes. Ghoname et al (5) varied the frequency of the active electrical stimulus at 3 levels, also comparing it with sham stimulation, in 68 patients. One level involved active stimulation with alternating 15-Hz and 30-Hz frequencies, while the other active levels had frequencies of 4 Hz and 100 Hz. The alternating frequency technique had the best results, superior to sham PENS. White et al (6) did not include sham PENS in a study of 72 patients. Rather, this study compared 4 montages, or patterns of needle placement. They found that a bottle-shaped pattern achieved the best results, compared with 3 other patterns. In addition, a 2003 study focused on chronic low back pain in community dwelling older adults. (7) Patients were randomized to receive twice weekly PEN or sham PENS for 6 weeks. At 3-month follow-up, the treatment group reported a significant reduction in pain intensity and disability while the control group did not.

While these studies suggest that active PENS has effects that exceed placebo PENS in the short term, it is unclear whether the study designs included adequate blinding. It is also unclear whether patients withdrew from these studies. Furthermore, the objective of treating chronic low back pain is long-term improvement of pain and functional outcomes, which none of these studies addresses. There is no evidence about the adverse effects of PENS or its acceptability over repeated courses of therapy. Therefore, the available evidence does not permit conclusions about the long-term effectiveness of PENS for treating low back pain.

Chronic Neck Pain

One study of 68 patients by White et al (8) compared 2 locations of active stimulation with sham stimulation in 68 patients. Local stimulation involved needle insertion at the neck, while remote stimulation entailed needles placed in the lower back. The sham condition received needles with no electrical stimulation at the neck. Outcomes were assessed immediately after completion of a 3-week treatment period. The local placement of active needles resulted in better pain relief, physical activity, quality of sleep, and analgesic use than local sham treatment or remote active treatment. The authors stated that no side effects were observed at needle insertion sites. The study was described as investigator blinded, but no details were given about the method of blinding. Withdrawals were not noted, and no long-term outcome data were presented. This single study, in which blinding is of uncertain adequacy, does not permit conclusions about the effectiveness of PENS for treating chronic neck pain.

Diabetic Neuropathy

In a crossover study by Hamza et al. (9), 50 patients with diabetic neuropathic pain for at least 6 months were randomized to receive either sham PENS or active PENS first in a 7-week study. Outcome was assessed 1 day after completion of a 3-week treatment period. Active PENS resulted in better outcomes on VAS pain, activity, sleep, and analgesic use, compared with sham PENS. The authors describe the study as investigator blinded, without providing details of how blinding was attempted. Thus, it is uncertain whether blinding was adequate. Withdrawals were not mentioned. Also, no long-term outcome data were presented, so long-term effects are unknown. This single study, which may not have been adequately blinded, does not allow conclusions about the effects of PENS for treating diabetic neuropathy.

Headache

Ahmed et al. (10) conducted a crossover study in 30 patients with longstanding headaches of 3 types: tension, migraine, and post-traumatic injury. Two-week courses of active and sham PENS were compared. Outcomes were assessed at the completion of each treatment. Active PENS achieved better outcomes than sham PENS in

terms of VAS pain, physical activity, and quality of sleep. Results did not vary by headache type. The investigators stated that the study was single-blinded, but gave no details about blinding methods or whether withdrawals occurred. The report offers no long-term outcome data. This study does not establish the effectiveness of PENS for treatment chronic headache.

Percutaneous Neuromodulation

From its description, neuromodulation appears to be a variant of PENS, varying in length of the needle and its placement at specific anatomical landmarks in the back, instead of specifically at the site of pain. A literature search identified 1 abstract focusing on neuromodulation. This study was an uncontrolled case series of 83 patients with low back pain. While pain improved at 5-week follow-up, the lack of a control group precludes scientific assessment. (11)

2005 Update

A 2005 literature review update for the period of 2004 through May 2005 identified only 1 randomized clinical trial comparing PENS to TENS treatment for chronic low back pain (LBP). (12) In this study, Yokoyama et al found patients that received PENS treatment twice per week for 8 weeks had significantly decreased pain levels, physical impairment, and NSAID use, which continued to be present 1 month after treatment completion compared to a second group that received PENS for 4 weeks followed by TENS for 4 weeks and a third group that received only TENS for 8 weeks. While PENS treatment for 8 weeks seemed to demonstrate greater effectiveness in controlling pain for up to 1 month after treatment when compared to the other treatment groups, the beneficial effects were not found at the 2-months follow-up. In addition, this study did not have a sham PENS group. Therefore, conclusions on the long-term effectiveness of PENS for treating low back pain cannot be made.

2006 Update

A literature review update for the period of March 2005 through April 2006 identified no new clinical trial publications. Therefore, the policy statement is unchanged.

2007 Update

A search of the MEDLINE database for the period of May 2006 to September 2007 identified 1 new clinical trial. This single-blinded trial randomized 70 patients with knee osteoarthritis to stimulation (at the highest tolerable intensity) or placement of electrodes (without stimulation). (13) Patients in the sham group were informed that they would not perceive the normal “pins and needles” with this new device. Patients received 1 treatment and were followed up for 1 week. The neuromodulation group had 100% follow-up; 7 of 35 (20%) patients from the sham group dropped out. VAS pain scores improved immediately after active (from 5.4 to 3.2) but not sham (5.6 to 4.9) treatments. VAS scores (4.6 vs. 5.2) were not significantly different for the 2 groups at 48 hours after treatment. Changes in the Western Ontario and McMaster Osteoarthritis Index (WOMAC) were significantly better for the category of stiffness (1 point change vs. 0 point change) but not for pain or function at 48 hours. Measures of patient satisfaction were significantly higher in the neuromodulation group (e.g., 77% vs. 11% good to excellent) at up to 1-week follow-up. Interpretation is limited by the discrepancy between patient satisfaction ratings and 48-hour VAS pain scores, and the differential loss to follow-up in the 2 groups. These results raise questions about the effectiveness of the blinding and the contribution of short-term pain relief and placebo effects to these results. Questions also remain about the duration of the treatment effects. Larger double-blinded studies with a more effective sham condition and longer follow-up are needed. Therefore, evidence remains insufficient to alter the conclusions reached above; the policy statement is unchanged.

Medicare Coverage Policy

The Centers for Medicare and Medicaid Services (CMS) currently has the following national coverage policy on PENS (14):

35-46 ASSESSING PATIENT'S SUITABILITY FOR ELECTRICAL NERVE STIMULATION THERAPY

“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:

B. Percutaneous Electrical Nerve Stimulation (PENS).--This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services that are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.7 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit. See §280.13 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.)

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