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April 12, 2012

Susan Miller, MD  
Lead Medical Officer  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: National Coverage Analysis (NCA) Proposed Decision Memo for  
Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-  
00429N)**

Dear Dr. Miller:

On behalf of our 82,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the National Coverage Analysis (NCA) Proposed Decision Memo for transcutaneous electrical nerve stimulation (TENS) for chronic low back pain (CLBP).

Within the memo – issued on March 13, 2012 – CMS proposes to limit Medicare coverage of TENS for CLBP to patients who enroll in an approved prospective clinical study addressing TENS efficacy and meeting other specified standards. APTA is concerned that this requirement to enroll in a clinical study is highly burdensome for the Medicare beneficiary and will severely limit patient access to medically necessary treatment utilized to improve overall function and health.

Physical therapists are licensed health professionals who evaluate and treat Medicare beneficiaries in a variety of practice settings including private practices, hospitals, skilled nursing facilities, home health agencies, rehabilitation agencies and comprehensive outpatient rehabilitation facilities. Within these settings, physical therapists play a vital role in the assessment and management of chronic pain. The TENS unit is among the many tools that a physical therapist may use to meet the needs of a patient with CLBP in combination with other interventions that account for the complexity of the patient.

As mentioned in our previous comments regarding this NCA, a national change in coverage for the TENS unit will have a major impact on the provision of services delivered by physical therapists and physical therapist assistants. Medicare has a

longstanding history of covering medically necessary TENS for beneficiaries through local coverage determinations (LCDs). While we understand CMS's desire to have additional evidence to support TENS effectiveness in CLBP treatment, we urge CMS to rescind its current national coverage proposal and continue to allow Medicare coverage of this modality through the existing LCDs. We also encourage additional research regarding the circumstances when the use of TENS for CLBP is effective. If this research development moves forward, we recommend that CMS convene a technical expert panel to further examine the issue. APTA has several member experts that could serve on this panel to aid CMS in this endeavor.

### **Evidence Does Support TENS Efficacy for CLBP When Utilized Appropriately**

Our previous comments, submitted October 13, 2011, highlighted several studies demonstrating positive outcomes for TENS when used appropriately to treat CLBP. CMS discounted many of the studies cited by APTA, stating that all studies in which authors claimed a TENS benefit were “hampered by methodologic limitations.” For example, CMS excluded the rigorous meta-analysis from Johnson and Martinson<sup>1</sup> including data from 38 randomized trials, which reported that TENS had a favorable pooled effect that was greater than placebo. Johnson and Martinson included patients with chronic ( $\geq 3$  months) musculoskeletal pain from various anatomical locations (including back, neck, hip, and knee). Their rationale for a “more inclusive” approach was that TENS mechanisms for pain relief are not specific to anatomical region. This meta-analysis demonstrated positive outcomes for the treatment of chronic pain by TENS, and should not be discounted simply because of this inclusive approach.

Further, APTA notes that the outcome measured in studies for TENS efficacy for CLBP is very important. For example, recent work with TENS shows that TENS has minimal effect on resting pain but may be better for pain with movement and could improve function.<sup>2</sup> The majority of studies cited by CMS in this memo only assess resting pain. Few studies have looked at measures beyond resting pain, and few have included function or quality of life as measures typically incorporated in clinical trials. CMS indicates its interest in this aspect of TENS with its second and third questions that must be addressed in the proposed clinical trial requirement in the proposed decision memo: does the use of TENS provide a clinically meaningful improvement in function and does the use of TENS provide a clinically meaningful reduction in other medical treatments or services used in the medical management of CLBP?

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1. Johnson M, Martinson M. Efficacy of electrical nerve stimulation for chronic musculoskeletal pain: a meta-analysis of randomized controlled trials. *Pain* 2007;130:157-165.
  2. Rakei B and Frantz R. Effectiveness of transcutaneous electrical nerve stimulation on postoperative pain with movement. *J Pain* 2003;4(8):455-464.

In adults over 60 years of age, another study<sup>3</sup> found an approximate 50% reduction in pain and reduced pain medication intake in subjects with chronic low back pain treated with TENS compared to acupuncture. CMS excluded this particular study, citing only “imprecise location of back pain” as the reason for exclusion. APTA respectfully disagrees that this is a meaningful reason for exclusion from this coverage analysis, as this study provides an affirmative answer to both of the questions posed in the proposed decision memo regarding meaningful functional improvement and meaningful reduction in other medical treatments. In addition, other existing reports<sup>4</sup> not considered by CMS highlight patient satisfaction with TENS regarding increased function, decreased reliance on pain medication, cost reduction due to the decrease in other medical treatment, and overall improvement in quality of life.

We disagree with the CMS decision to discount the aforementioned evidence supporting TENS treatment for CLBP, as we believe this evidence is sufficient to continue its Medicare coverage.

### **A National, Restrictive Coverage Policy Is Inappropriate for TENS**

In its proposed memo, CMS acknowledges that “the absence of conclusive evidence of benefit does not equate to conclusive evidence of no benefit.” Evidence does exist to support the efficacy of TENS for the treatment of CLBP, albeit evidence that does not meet the stringent qualifications to prevent exclusion from this NCA’s consideration. The absence of evidence meeting these methodologic standards may in fact illuminate a need to conduct new studies regarding TENS effectiveness for CLBP. This absence does not, however, equate to “no benefit” and it does not merit a national restrictive coverage policy that will create further burdens for patients seeking this treatment as well as limit access to many who cannot overcome such burdens.

Therefore, APTA appreciates the need for further evidence development regarding this issue, but we do not support conducting such research at the expense of CLBP patient access to TENS treatment. We believe that if CMS decides to require evidence development for CLBP TENS treatment, such a requirement should not be through the use of a coverage with evidence development (CED) policy. CED policies may be appropriate under some circumstances, such as testing efficacy in the advent of new medical technologies. However, revoking the longstanding coverage of an existing

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3. Grant DJ, Bishop-Miller J, Winchester DM, Anderson M, Faulkner S. A randomized comparative trial of acupuncture versus transcutaneous electrical nerve stimulation for chronic back pain in the elderly. *Pain* 1999;82:9-13.

4. Chabal C, Fishbain DA, Weaver M, Heine LW. Long-term transcutaneous electrical nerve stimulation (TENS) use; impact on medication utilization and physical therapy costs. *Clin J Pain*. 1998 Mar;14(1):66-73

Fishbain DA, Chabal C, Abbott A, et al. Transcutaneous electrical nerve stimulation (TENS) treatment outcome in long-terms users. *Clin J Pain* Sep;12(3):201-214.

treatment that already has adequate medical necessity assessment safeguards is not an appropriate use of a CED policy.

According to the CMS guidance for “National Coverage Determinations with Data Collection as a Condition for Coverage: Coverage with Evidence Development,” two options for CED are identified: Coverage with Study Participation (CSP), under which CMS provides coverage only to patients enrolled in an approved clinical research study that meets certain rigorous standards; and Coverage with Appropriate Determination (CAD), under which additional clinical data must be submitted by the provider to a database or registry as a condition of the beneficiary’s coverage. We contend that this proposed use of a CSP for existing covered services through a National Coverage Determination (NCD) is inconsistent with the stated purpose of an NCD. Section 1869(f)(1) of the Social Security Act defines an NCD as “a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII...” These determinations are made through an evidence-based process to determine whether items or services are reasonable and necessary within the scope of the Medicare benefit. The use of TENS for CLBP has already been deemed reasonable and necessary under certain circumstances through both national and local coverage policies. We believe that using an NCD to require further research through CSP for a well-established treatment does not meet the original thrust that the NCD process was created to carry out.

As a result, APTA urges CMS to remove the requirement that CLBP patients must enroll in a prospective medical study in order to receive Medicare coverage for TENS. Should CMS decide to proceed with an evidence development requirement, we believe that Medicare beneficiaries should still receive coverage for TENS under the current LCDs.

### **Standards within Local Coverage Determinations Adequately Address Medical Necessity for TENS Use**

In addition to our patient access concerns, APTA is also concerned that this restrictive national policy will eliminate the current appropriate medical necessity assessments by local Medicare Administrative Contractors (MACs). Each Durable Medical Equipment (DME) MAC has established strict criteria for reasonable and necessary treatment with TENS within their LCDs. Among these standards required in all four LCDs is the requirement of a 30-day trial period; failure of other attempted treatment modalities; the presence of pain for over three months; a presumed pain etiology that is accepted as responding to TENS; adequate documentation of therapeutic benefit; and reevaluation documented after the trial period.

The trial required by all four DME MACs addresses the issue of appropriate application of TENS. TENS must be tailored to each patient in an attempt to determine if the patient is a TENS responder or non-responder. Patients are entitled to a trial administered by a therapist who understands the clinical responses and is capable of making appropriate adjustments. These adjustments include a determination of the proper combination of

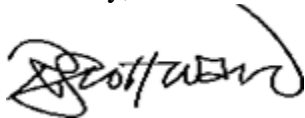
electrode placement, stimulus amplitude, frequency, pulse width, and other modulations that might help the individual patient.

We believe that a successful trial, along with the other standards established by the DME MACs, establishes sufficient safeguards to ensure TENS treatment is medically necessary and appropriate for the patient. Therefore, we strongly believe that CMS should defer to the review of medical necessity on the local MAC level instead of implementing a national policy that hinders patient access to medically necessary services.

### **Conclusion**

APTA greatly appreciates the opportunity to comment on the efficacy of the TENS unit on chronic low back pain. We urge CMS to remove the CED requirement from this proposed decision. Instead, we recommend that CMS continue to make the benefit of this modality available to Medicare beneficiaries with chronic low back pain through local policies if coverage development is required. If you have any questions regarding our comments, please contact Gillian Russell, Senior Regulatory Affairs Specialist, at 703-706-3189 or [gillianrussell@apta.org](mailto:gillianrussell@apta.org).

Sincerely,

A handwritten signature in black ink, appearing to read "R. Scott Ward". The signature is stylized and cursive.

R. Scott Ward, PT, PhD  
President

RSW:glr

Cc: Louis Jacques, MD  
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