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October 13, 2011

Susan Miller, MD
Centers for Medicare and Medicaid Services
7500 Security Boulevard
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Re: National Coverage Analysis (NCA) Tracking Sheet for Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain (CAG-00429N)

To Whom It May Concern:

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) for transcutaneous electrical nerve stimulation (TENS) for chronic low back pain.

Role of Physical Therapists in Chronic Low Back Pain Treatment

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.

Physical therapists evaluate and treat patients to assist them in maintaining or increasing their function and mobility through strengthening, increasing their ability to participate in activities of daily living, prescribing assistive technologies and equipment, and promoting appropriate physical activity. Physical therapist interventions aim to reduce pain, while increasing and maximizing joint mobility, muscle strength, flexibility, and aerobic capacity, and preventing functional loss. These interventions include: therapeutic exercise; manual therapy, including mobilization and manipulation; functional training in self-care, home management, and work; integumentary repair and protective techniques; physical agent modalities (e.g. TENS); and patient-related instruction and education. The TENS unit is therefore among the many important tools that a physical therapist uses to meet the needs of the patient.

As a result, 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 long-standing history of covering medically necessary TENS for beneficiaries through local coverage determinations (LCDs). We urge CMS to (1) continue to allow Medicare coverage of this modality due to the proven positive health outcomes attributable to the treatment of chronic low back pain with TENS and (2) ensure that physical therapists continue to be among the health care providers qualified to treat with TENS.

Study Used by CMS in NCA Not Conclusive on Efficacy of TENS for Chronic Low Back Pain

The recent systematic review by Dubinsky and Miyasaki, on which CMS bases its NCA, asserts that “TENS is not recommended for the treatment of chronic low back pain due to lack of proven efficacy” (Dubinsky and Miyasaki[1]). This assertion was based only on two studies (Warke et al[2] and Deyo et al[3]). The first studied back pain in people with multiple sclerosis (MS) and it is likely that the pain of MS is related to direct injury and permanent damage to the central nervous system. Because a study of pain in MS patients cannot adequately represent the vastly complex patient population with chronic low back pain, CMS should not use this study, in isolation, to create a coverage policy for all Medicare beneficiaries.

The second study, conducted by Deyo and colleagues, compared TENS with and without exercise to sham TENS with and without exercise in patients with chronic low back pain. The subjects were given a period of high frequency TENS, switched to a period of low frequency TENS, and then chose their preferred treatment. Intensity was applied by having subjects set the amplitude to a pre-designated setting on the machine. The type or intensity of stimulation in the patient-selected setting was not reported even though the patient’s preferred mode was the author’s primary outcome measured in the study.

Recent data show that stimulation intensity and adequate dosing are critical for TENS to be effective (Rakel 2003[4]; Bjordal 2003[5]; Rakel 2009[6]). In fact, a study on postoperative pain conducted by Bjordal and colleagues divided groups into those that used adequate stimulation intensity (‘strong but comfortable’) and those that did not use this intensity. In this systematic review, only those receiving the adequate dose saw a positive response (reduction in opioid consumption).

The Deyo study fails to report the intensity of stimulation, and therefore, its outcome measure cannot assess whether subjects received adequate TENS dosage. Because dosage adequacy is essential for TENS effectiveness, the Deyo study fails to sufficiently capture TENS efficacy in chronic low back pain patients.

Evidence Does Support TENS Efficacy for Chronic Low Back Pain When Utilized Appropriately

Existing evidence does suggest TENS efficacy when used to treat chronic low back pain. Perhaps more important, however, are several significant factors that should be considered regarding the appropriate utilization of TENS. We believe that CMS should

consider the following relevant literature and subsequent relevant factors, which show when TENS is a viable and appropriate intervention for patients with chronic low back pain.

Studies Showing Positive Outcomes

First, and most notably, numerous studies show positive health outcomes attributable to TENS. For example, a rigorous meta-analysis from Johnson and Martinson including data from 38 randomized trials reported that TENS had a favorable pooled effect that was greater than placebo.[7] Johnson and Martinson included patients with chronic (≥ 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. A meta-analysis was performed so that the effects of all studies were considered in the conclusions that TENS had a greater favorable effect than placebo. Johnson and Martinson did not specifically address the clinical relevance of their findings, but they did perform a sensitivity analysis that indicated the lower quality studies did not bias results.

A study also showed a participant-reported pain reduction of 70-80% with the use of TENS as compared to massage.[8] In adults over 60 years of age, another study 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.[9] Further, Leonard and colleagues studied the efficacy of low and high frequency TENS in opioid-tolerant patients as well as those who were not opioid tolerant.[10] The majority of the patient population in this trial had spine pain. The study showed a significant reduction in pain during and immediately after conventional TENS, or high frequency, when compared to baseline for both the opioid and non-opioid group. For low frequency TENS, the analgesic effect was only observed in the non-opioid group. This further proves the importance of adequate dosage in the efficacy of TENS.

Outcomes Measured in TENS Treatment

Second, APTA notes that the outcome measured in these studies 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 (Rakel 2003; Dailey 2010). The majority of studies 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. It is our belief that if a person’s function can be improved with TENS allowing greater participation in daily activities, even without a concurrent reduction in pain, the modality has merit. Likewise, if a person can minimize their reliance on pain medications, the modality may be a better option for select individuals. The following reports by Chabal and Fishbain highlight patient satisfaction with TENS regarding increased function and decreased reliance on pain medication[11][12]:

- For 376 randomly chosen patients who had been using a TENS device for six months or longer, telephone interviews were conducted by an independent research firm, focused specifically on changes in medication use, number of pain-related medications, and use of physical therapy and occupational therapy prior to using TENS and then after a minimum of six months of TENS use. As compared to the period prior to TENS use, these patients reported a statistically significant reduction in use of opiate analgesics, tranquilizers, muscle relaxants, NSAIDs, and steroids. Physical and occupational therapy use was also significantly reduced. Cost simulation on the data showed that TENS use could reduce costs for medications by 55% and up to 69% for physical and occupational therapy.
- Additionally, in 506 randomly selected patients who had purchased a TENS unit for pain were contacted from a list of 2,003 possibilities. These long-term users were surveyed by telephone interviews to assess changes or improvements that paralleled the introduction of TENS. Significant improvements were noted in less pain interference with work, home, and social activities; increased activity level and pain management; decreased use other therapies (e.g. physical therapy, occupational therapy, chiropractic); decreased use of narcotics, tranquilizers, muscle relaxants, nonsteroidal anti-inflammatory drugs, and steroids.

Isolated Use of TENS

Finally, chronic low back pain can occur from multiple different conditions including non-specific low back pain, musculoskeletal, neuropathic pain, and from neurological disorders such as MS. Chronic low back pain, like all forms of chronic pain, is a complex clinical phenomenon influenced by biological, psychological, environmental, and social factors. It is highly unlikely that effective treatment for chronic pain will ever be linked to an isolated treatment (pharmacological or non-pharmacological). Furthermore, nearly all patients with chronic pain receive multiple treatments. Yet, TENS is often included in research studies as an isolated treatment. Therefore, associated treatment recommendations of these studies may be limited to isolated use of TENS.

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

APTA is concerned that the development of a national policy will limit local Medicare contractors' ability to assess the medical necessity of TENS treatment. In fact, each Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) has already 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.

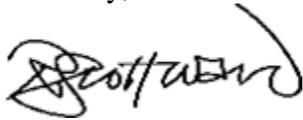
The trial required by all four DME MACs addresses the aforementioned issue of appropriate application of TENS. TENS must be tailored to each patient in an attempt to determine if the patient is a TENS responder or non-responder. Patients are entitled to a trial administered by a therapist who understands 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.

Conclusion

APTA greatly appreciates the opportunity to comment on the efficacy of the TENS unit on chronic low back pain. We urge CMS to continue to make the benefit of this modality available to Medicare beneficiaries with chronic low back pain. If you have any questions regarding our comments, please contact Gillian Russell, Assistant Director, Regulatory and Payment Counsel, at 703-706-3189 or 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: Sarah Meisenberg, MSPH
Brijet Burton, MPP, MS, PA-C

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