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Dear Sir/Madam:

I am writing you in response to the CMS Review of the National Medicare Coverage of the use of transcutaneous electrical nerve stimulation (TENS) for chronic low back pain. I am aware of other letters that have been sent to you on this subject by peers of mine who deserve the greatest respect. I am aware of the letter of Florida Society of Interventional Pain Physicians. I am aware of the letter by Dr. Kathleen A. Sluka, PT, PhD. In addition, I have seen a letter by Dr. Jeffrey Zipper, Chairman of Medical Affairs and Legislative Committee for the Florida Academy of Pain Medicine.

I am writing this letter on behalf of myself and other doctors of Physical Medicine and Rehabilitation in the State of Florida. I attended college at Brandeis University in Waltham, Massachusetts. I later attended medical school at the Washington University School of Medicine in St. Louis, Missouri. I completed an internship in Internal Medicine at Albert Einstein College of Medicine in the Bronx, New York and later completed specialty training in Physical Medicine and Rehabilitation at the Thomas Jefferson University Hospital in Philadelphia, Pennsylvania. I hold a fellowship from the American Academy of Physical Medicine and Rehabilitation. I am a fellow of the American Board of Electrodiagnostic and Neuromuscular Medicine. I hold subspecialty certification by the American Board of American Specialties in Pain Management.

I have treated patients with back pain for the past 25 years and I would agree with previous authors that chronic low back pain is generally multi-factorial in nature. It originates with anatomic structures in the back including musculoskeletal tissue, muscles, facet joints, lumbar disks, sacroiliac joints, just to mention a few of the more common causes.

The State of Florida claims more deaths from prescription drug abuse than any other state in the nation. According to the Center for Disease Control, approximately seven people die in Florida each day primarily from the use of prescription narcotic medications. Approximately 13 people per day die in our state where the use of controlled substances is a contributing factor. Only recently has Florida enacted legislation to help limit the spread of narcotic medication deaths by dispensers including untrained physicians who have been responsible for the growth of narcotic treatment for chronic low back pain.

As a result, I have struggled to locate treatments for low back pain that are not dangerous to the patient. I regularly employ the use of physical therapy, exercise, stretching, massage. There are a series of medications which do not have addictive potential which are very useful for chronic low back pain. I refer to Cymbalta, Lyrica, a variety of dual-mechanism anti-depressants including Elavil, Effexor, muscle relaxers, etc. In many cases the medications we use are not indicated for the treatment of back pain, however, they are effective and they represent an alternative to the use of addictive narcotic medications.

Transcutaneous nerve stimulation (TENS) has been a helpful alternative for my patients over the past 25 years in the treatment of back pain. TENS is a safe, non-addictive relatively inexpensive and effective intervention that represents a viable alternative to much more expensive or dangerous interventions. If you were to limit access of Medicare and Medicaid patients to TENS stimulation you would be removing one of the more effective and safer tools that a pain physician has to use in the battle against back pain. In fact, I believe you would push people to using addictive and narcotic medications as you would be removing a safer, more effective and inexpensive alternative.

As you may know, TENS is the application of electrical current through the skin for pain control. Its effectiveness is based upon the gate control theory of pain which was originated by Melzack and Wall in the 1960s. To describe the idea of TENS in a comprehensible format, try to imagine pain as a sensation which travels from the back through peripheral nerves in the spinal cord up to the brain. As this signal moves along the spinal cord up to the brain, there are cells within the spinal cord that can either increase the severity of the pain or decrease the severity of the pain. These cells live within the spinal cord and are called "interneurons." They have the power to lessen the severity of pain transmitted to the brain. TENS represents a mechanism of activation of these interneuron cells which in turn lessen the magnitude of pain transmitted to the brain. In a sense, TENS works very much like a pain pill. It does not change the organ which is causing the pain, however, it does affect the signal which the body transmits from the source of pain to the brain, thus changing a person's perception.

Think of a person who burns his hand on the stove. His first reaction is to jerk the hand away and to scream. He then shakes his hand. He then continues to yell and scream in some cases, expletives. He puts the burnt hand under cold water.

This behavior is universal. It does not matter if the man who receives the injury is in Mexico, America or China. It does not matter if the victim is a man or woman, old or young.

The behavior is universal. I pose the question to you: Why do we go through all of these behaviors in response to an injury? Certainly yelling, crying or rubbing a burnt hand or placing it under cold water does not limit the thermal damage which has taken place to the tissue, yet all of us have this reaction. I propose that the reason we engage in this behavior is that each of these activities provides a competing sensation to the sensation of pain. If the man yells loud enough, shakes the hand enough, puts the hand under cold water long enough, the feeling of the burn is somehow lessened. This reduction in the magnitude of pain which occurs from the competing sensations that I have outlined above takes place via the same interneurons in the spinal cord which are the target of a TENS unit.

There are numerous trials that have documented the effectiveness of TENS. These trials have used a variety of different methodologies comparing TENS to treatments such as massage or acupuncture. The intensity of the TENS unit is critically important in obtaining a positive effect as the intensity of stimulation must be of sufficient strength to gain an analgesic response. I refer you to Moran F. et. al., "Hypoalgesia in Response to Transcutaneous Electrical Nerve Stimulation (TENS) Depends on Stimulation Intensity." *Journal of Pain* 2011; 12:929-935. I also refer you to the paper by Rakel B. et. al., "A New Transient Sham TENS Device Allows for Investigator Blinding While Delivering a True Placebo Treatment." *Journal of Pain* 2010; 11: 230-238. These papers demonstrate that TENS delivered at a strong but comfortable intensity provides a significant analgesic effect while TENS delivered at or below sensory threshold is ineffective.

In addition, a rigorous meta-analysis from Johnson and Martinson (Johnson M. et. al, "Efficacy of electrical nerve stimulation for chronic musculoskeletal pain: a meta-analysis of randomized controlled trials." *Pain* 2007; 130: 157-165). This study reported that TENS has a favorable pooled effect after the evaluation of 27 randomized trials and reported that TENS has a favorable pooled effect which is greater than placebo.

Machado and colleagues (Machado LA, et. al., "Analgesic effects for treatments for non-specific low back pain: a meta-analysis of placebo controlled randomized trials." *Rheumatology (Oxford)* 2009; 48: 520-527) performed a meta-analysis of TENS effectiveness when compared to placebo for patients with low back pain. In this meta-analysis the data were restricted to people with non-specific low back pain. They included four trials and concluded that there is a favorable effect in reducing pain with the active TENS when compared to a placebo. This effect was considered moderate compared to placebo.

In contrast to the above trials, CMS used a systematic review by Dubinsky and Miyasaki to make the following recommendation: “TENS is not recommended for the treatment of chronic low back pain due to lack of proven efficacy.” Please note that the paper by Dubinsky and Miyasaki was based on transcutaneous nerve stimulation in patients with multiple sclerosis who had low back pain.

As you may know, patients with multiple sclerosis have a series of pain issues related to the central nervous system and not to the low back at all. Treatments that are very effective for the great majority of patients with chronic low back pain have no effect whatsoever in patients with multiple sclerosis. As a demonstration of the futility of using this population, imagine if we tested the effect of steroids on athletic performance in multiple sclerosis patients and then concluded that since their athletic performance did not improve in the same way that other steroid-enhanced athletes improved, that steroids are ineffective for enhancing athletic performance. I believe you see that the comparison is unfair. It is certainly unscientific. There are no firm conclusions that can be drawn from examining patients in this group.

The second study used by Dubinsky and Miyasaki was performed by Deyo and colleagues. It compared the use of TENS with and without exercise to sham TENS with and without exercise in patients with chronic low back pain. Unfortunately there is no mention of the intensity of TENS stimulation used and as a result, no conclusion whatsoever can be drawn. As you know, intensity of stimulation is a critical factor in evaluating the effectiveness of TENS.

In summary, there is a wealth of evidence supporting the use of TENS in the treatment of chronic low back pain. I have only scratched the surface in the papers that I have listed above. TENS has a well-established track record, a firm theoretical basis and copious amounts of personal clinical experience that substantiate its use. Eliminating TENS would chip away at the arsenal that pain physicians have to treat patients with chronic pain, pushing those patients to the use of narcotic and addictive substances. I implore you to allow patients to continue to receive the use of this effective, economical and safe intervention for chronic pain.

Please contact me with any questions regarding the above opinions.

Sincerely,

Jesse A. Lipnick, M.D.  
JAL/dhw