



IMED, INC.

11625 Custer Road • Suite 110-343 • Frisco, Texas 75035
Office 972-381-9282 • Toll Free 1-877-333-7374 • Fax 972-250-4584
e-mail: imeddallas@msn.com

Notice of Independent Review Decision

DATE OF REVIEW: 04/12/10

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute: TENS unit purchase (2-Lead)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

Texas Board Certified Internal Medicine and Occupational Medicine

REVIEW OUTCOME

Upon independent review, the reviewer finds that the previous adverse determination/adverse determination should be:

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Chiropractic treatment records. 9/16/09-3/1/10.
2. Clinical records Dr. 10/14/09-3/3/10
3. Radiographic report thoracic spine dated 09/16/09, 10/13/09
4. Radiographic report lumbar spine dated 09/16/09.
5. MRI thoracic spine dated 09/15/09.
6. Pain management note Dr. dated 11/03/09.
7. Clinical note Dr. 2/2/10
8. Utilization review determination dated 02/24/10.
9. Utilization review determination dated 03/04/10.
10. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):

The employee is a male who is reported to have sustained work related injuries on xx/xx/xx. He reports that on 09/11/09 he was at a hospital transferring a patient from a stretcher board to a bed when he injured his back. He specifically bent over to lift the patient and rotated to his right and while lifting experienced immediate onset of pain which is most intense in the mid thoracic spine but associated with pain down the low back and occasionally spread to the right thigh. He was referred to the xxxxxx by supervisor for treatment. They were not his first choice of doctor but since he was directed to go there he went for a visit and was given a prescription for Flexeril and Hydrocodone. No radiographs were taken. The employee subsequently sought care from, D.C. on 09/16/09. At this time the employee reports a past medical history of low back pain and has been diagnosed with an L3-4 disc herniation in the past prior to this

accident. He was having ongoing trouble with his low back pain. Records indicate that he is able to ambulate without assistive devices. He is able to receive pinwheel and vibration equally in the upper extremities and his reflexes are 2+ and brisk in the lower extremities with strength graded as 5+ in the lower extremities. He is tender through the mid lumbar spine and lumbosacral region and most focally tender over the spine at T9-10 with moderate to severe spasm. Supine straight leg raise is 60 degrees bilaterally with increased pain. He is able to stand on his toes and heels without difficulty and he is able to forward flex to 70 degrees and he has pain with extension at 5 degrees. The employee is opined to have a thoracolumbar strain with spasm. He subsequently was taken off work and he was recommended to undergo a conservative course of chiropractic physiotherapy. The record includes a radiographic report dated 09/16/09. The employee is reported to have a minimal S-shape curvature of the mild vertical disc space narrowing of the mid thoracic spine. Radiographs of the lumbar spine were performed on 09/16/09. This study reports a developmental anomaly from L5-sacrum with disc plastic posterior elements of L5 and S1 and pseudo articulations between S1 and S2. There is segmental instability at L1-2, L2-3, L3-4 and L4-5 with only minimal vertical disc space narrowing. This study reports a retrolisthesis of L1-2 and L2-3, 2 mm of anterolisthesis of L1-2. The record indicate that the employee underwent MRI thoracic spine on 10/13/09. This shows multi level thoracic disc herniations from T4-5 to T8-9 with multi level cord compression. The employee was referred for pain management on 11/03/09. At this time the employee was seen by Dr. The employee is reported to have undergone injections and appears to have developed myofascial swelling as a side effect from steroids. He was subsequently recommended not to undergo any additional injections. The employee was later seen by Dr. on 10/14/09. Dr. recommends additional corticosteroid injections into the thoracic spine. When seen in follow up on 11/30/09 he reports 60-70 percent pain relief. He subsequently underwent a second series of injections on 12/14/09 and received an overall 70 percent reduction. The employee was later seen by Dr. on 02/02/10. He is opined not to be a surgical candidate. The employee was subsequently recommended to utilize a TENS unit.

The request was initially reviewed on 02/24/10. The reviewing physician reports that ODG does not support the use of these devices in the treatment of chronic pain and subsequently does not recommend approval of the request. A second review was performed by an unidentified physician on 03/04/10. This reviewer indicates that ODG does not support inferential stimulators and notes that randomized trials that have evaluated the effectiveness of this treatment have included studies for back pain, jaw pain, soft tissue shoulder pains, cervical and neck pain and post operative knee pain.

These findings were either negative or non interpretable for recommendations due to poor study of design and/or methodological issues. In regards to TENS, he reports a TENS trial may be considered as a non invasive conservative treatment option when used as an adjunct to a program of evidence based functional restoration. He notes that long term effectiveness and improved injury outcomes have not been established and he therefore is not endorsing this request.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION.

The submitted clinical record indicates that the employee sustained thoracolumbar and myofascial strain as a result of lifting a employee on the date of injury. The record indicates the employee has received extensive conservative treatment including 29 sessions of chiropractic modalities. The employee has undergone multiple imaging studies which indicate the presence of degenerative disease in the lumbar spine with thoracic disc protrusions per MRI dated 10/13/09. The employee has undergone interventional procedures and is noted to have 70 percent improvement with thoracolumbar ESIs. He subsequently has been recommended to receive a TENS unit for permanent use. Current evidence based guidelines do not support the use of TENS in the treatment of chronic myofascial pain. There are limited clinical studies which fail to establish this to be efficacious treatment. Based upon the submitted clinical information and the 2 previous utilization reviews, the denial of the request for purchase of a TENS unit is upheld.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION

The 2010 *Official Disability Guidelines*, 15th Edition, The Work Loss Data Institute. Online Edition.

TENS, chronic pain (transcutaneous electrical nerve stimulation)

Not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based [functional restoration](#), including reductions in medication use. for the conditions described below. While TENS may reflect the long-standing accepted standard of care within many medical communities, the results of studies are inconclusive; the published trials do not provide information on the stimulation parameters which are most likely to provide optimum pain relief, nor do they answer questions about long-term effectiveness. ([Carroll-Cochrane, 2001](#)) Several published evidence-based assessments of transcutaneous electrical nerve stimulation (TENS) have found that evidence is lacking concerning effectiveness. One problem with current studies is that many only evaluated single-dose treatment, which may not reflect the use of this modality in a clinical setting. Other problems include statistical methodology, small sample size, influence of placebo effect, and difficulty comparing the different outcomes that were measured.

Recommendations by types of pain: A home-based treatment trial of one month may be appropriate for neuropathic pain and CRPS II (conditions that have limited published evidence for the use of TENS as noted below), and for CRPS I (with basically no literature to support use).

Neuropathic pain: Some evidence ([Chong, 2003](#)), including diabetic neuropathy ([Spruce, 2002](#)) and post-herpetic neuralgia. ([Niv, 2005](#))

Phantom limb pain and CRPS II: Some evidence to support use. ([Finsen, 1988](#)) ([Lundeberg, 1985](#))

Spasticity: TENS may be a supplement to medical treatment in the management of spasticity in spinal cord injury. ([Aydin, 2005](#))

Multiple sclerosis (MS): While TENS does not appear to be effective in reducing spasticity in MS patients it may be useful in treating MS patients with pain and muscle spasm. ([Miller, 2007](#))

Recommendations for specific body parts (See specific body-part chapters below):

Low back: Not recommended as an isolated intervention

Knee: Recommended as an option for osteoarthritis as adjunct treatment to a therapeutic exercise program

Neck: Not recommended as a primary treatment modality for use in whiplash-associated disorders, acute mechanical neck disease or chronic neck disorders with radicular findings

Low Back:

TENS (transcutaneous electrical nerve stimulation)

Not recommended as an isolated intervention, but a one-month home-based TENS trial may be considered as a noninvasive conservative option for chronic back pain, if used as an adjunct to a program of evidence-based [conservative care](#) to achieve [functional restoration](#), including reductions in medication use.

Acute: Not recommended based on published literature and a consensus of current guidelines. No proven efficacy has been shown for the treatment of acute low back symptoms. ([Herman, 1994](#)) ([Bigos, 1999](#)) ([van Tulder, 2006](#))

Chronic: Not generally recommended as there is strong evidence that TENS is not more effective than placebo or sham. ([Airaksinen, 2006](#)) There is minimal data on how efficacy is affected by type of application, site of application, treatment duration, and optimal frequency/intensity. ([Brousseau, 2002](#)) There are sparse randomized controlled trials that have investigated TENS for low back pain. One study of 30 subjects showed a significant decrease in pain intensity over a 60-minute treatment period and for 60 minutes after. ([Cheing, 1999](#)) A larger trial of 145 subjects showed no difference between placebo and TENS treatment. ([Devo, 1990](#)) Single-dose studies may not be effective for evaluating long-term outcomes, or the standard type of use of this modality in a clinical setting. ([Milne-Cochrane, 2001](#)) ([Sherry, 2001](#)) ([Philadelphia Panel, 2001](#)) ([Glaser, 2001](#)) ([Maher, 2004](#)) ([Brousseau, 2002](#)) ([Khadikar, 2005](#)) ([Khadikar2, 2005](#)) Although electrotherapeutic modalities are frequently used in the management of CLBP, few studies were found to support their use. Most studies on TENS can be considered of relatively poor methodological quality. TENS does not appear to have an impact on perceived disability or long-term pain. Highfrequency TENS appears to be more effective on pain intensity when compared with low frequency, but this has to be confirmed in future comparative trials. It is also not known if adding TENS to an evidence-based intervention, such as exercise, improves even more outcomes, but studies assessing the interactions between exercise and TENS found no cumulative impact. ([Poitras, 2008](#)) For more information, see the [Pain Chapter](#).

Recent research: A recent meta-analysis concluded that the evidence from the small number of placebo-controlled trials does not support the use of TENS in the routine management of chronic LBP. There was conflicting evidence about whether TENS was beneficial in reducing back pain intensity and consistent evidence that it did not improve back-specific functional status. There was moderate evidence that work status and the use of medical services did not change with treatment. Patients treated with acupuncture-like TENS responded similarly to those treated with conventional TENS. ([Khadikar-Cochrane, 2008](#))