

C-IRO, Inc.
An Independent Review Organization
7301 Ranch Rd. 620 N, Suite 155-199
Austin, TX 78726

Notice of Independent Review Decision

DATE OF REVIEW: OCTOBER 28, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

TENS UNIT (4+ LEADS)

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

MD, Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

The reviewer finds that medical necessity does not exist for TENS UNIT (4+ Leads)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Adverse Determination Letters, 8/26/08, 10/2/08
ODG Guidelines and Treatment Guidelines
MRI of Cervical Spine, 1/23/07, 5/16/08
Cervical Spine, 7 views, 1/18/07
Thoracic Spine, 2 views, 1/18/07
MRI of Right Shoulder, 1/18/07
Chiropractic, 2/23/08, 6/13/08, 8/8/08, 9/5/08, 5/16/08, 7/11/08, 10/3/08, 3/21/08, 2/8/08,
11/7/07, 1/25/08, 12/20/07, 11/27/07, 11/1/07, 8/17/07, 7/16/07, 7/11/07, 6/7/07, 5/9/07,
4/4/07, 3/12/07, 2/19/07, 1/30/07, 1/26/07, 1/22/07, 1/10/07, 12/4/07
Evaluation Center, 2/21/08, 9/3/08
MD, 2/18/08, 9/3/08

MD, 4/3/07

Dr. 8/6/07

Daily Treatment Log, 1/4/08, 1/3/08, 1/2/08, 12/28/07, 12/27/07, 12/20/07, 12/19/07, 12/18/07, 7/6/07, 7/3/07, 6/27/07, 6/25/07, 6/22/07, 6/20/07, 6/19/07, 6/13/07, 6/11/07, 6/7/07, 5/31/07, 5/21/07, 6/1/07, 6/6/07, 2/12/07, 2/14/07, 5/23/07, 5/25/07, 5/29/07, 6/4/07, 5/18/07, 4/23/07, 4/18/07, 2/19/07, 2/16/07, 2/9/07, 2/8/07, 2/5/07, 1/31/07, 1/29/07, 1/26/07, 1/25/07, 1/22/07, 1/19/07, 1/15/07, 1/10/07, 1/11/07, 1/7/07

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a male who originally had an injury and an anterior cervical fusion from C5 to C7 from a xxx cervical injury. The new injury reportedly happened on xx/xx/xx. He had pain about his shoulders and numbness to the right 4th and 5th fingers (presumably digits). An MRI of the shoulder on 1/18/07 was suspicious for a partial tear of the rotator cuff. He underwent an acromioplasty on 4/27/07 and reportedly had significant symptom improvement. He had ongoing symptoms in the upper extremities. The cervical MRI done 1/23/07 reported a solid fusion. There was a disc bulge at C3-4 that did not compromise the cervical canal. There was stenosis from C4-5 from a disc bulge and protrusion. The C5/6 fusion was reported as solid. Flexion/Extension xrays on 1/18/07 suggested instability at C4/5. He had some degenerative changes in the cervical and thoracic spine. An emg on 8/6/07 showed no evidence of a radiculopathy or focal nerve compression. He had some transient relief after a series of cervical epidural injections in October 2007 and January 2008. This gave some relief. He apparently had a sacroiliac injection in February 2008, but this was not related. He underwent an FCE and impairment rating on 2/23/08. Subsequent DD ratings differed. A repeat MRI on 5/16/08 showed the postoperative changes at C5/6 without any cord compression. There is a small central annular tear at C3/4 without root compression or disc protrusion. There was a possible tear at C4/5 again without cord or root compression. Ongoing examination showed bilateral reduction in pinwheel and vibratory sensation, more on the left than the right. Requests for repeat ESIs were denied and the man had some improvement with prednisone in 8/2008. TENS was requested for symptom relief.

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

The ODG first addresses a month use for the TENS as an adjunct to functional restoration pain programs. The ODG cites the questions related to the effectiveness and outcomes of a TENS unit. The ODG does recognize that the TENS unit may be justified for neuropathic pain, but not as a primary treatment for chronic neck pain with radicular findings. At the same time, CMS accepts the use of the TENS unit for chronic intractable pain, but only after a one month trial. Its effectiveness must be documented in this trial after other treatment means failed. The ODG also advises the use of a 2 lead unit unless there is documentation and explanation for a 4 lead unit. That was not provided in the material reviewed. The reviewer can only approve or reject the specific request for a 4 lead unit. I must therefore reject this request. Dr. cited his objections to the use of the ODG as a set of guidelines stating that guidelines can be overruled. This can be done when there is adequate documentation to show that the ODG does not apply. In this case, the ODG will approve a 2 lead unit unless there is evidence provided why the 4 lead is more appropriate. That information was not provided. The reviewer finds that medical necessity does not exist for TENS UNIT (4+ Leads)

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](#), 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

Ankle and foot: Not recommended

Elbow: Not recommended

Forearm, Wrist and Hand: Not recommended

Shoulder: Recommended for post-stroke rehabilitation

How it works: TENS consists of an electrical pulse generator connected to skin-surface electrodes that apply stimulation to peripheral nerves at well-tolerated frequencies. Electrodes can either be placed at the site of pain or other locations, using a trial and error methodology. A TENS unit can be varied by amplitude, pulse width (duration) and pulse rate (frequency). The most common applications include (1) high frequency or conventional TENS (40-150 Hz, with a short duration of up to 50 microseconds) and (2) low frequency or acupuncture-like TENS (1-4 Hz at a high stimulus intensity). Other modes of TENS include: (1) brief-intense TENS (>80 Hz); (2) burst TENS (bursts at less than 10 Hz) at high frequency; and (3) modulation TENS. The difference between clinical effectiveness of the modalities has not been well defined. ([Koke, 2004](#))

Recent studies: There has been a recent meta-analysis published that came to a conclusion that there was a significant decrease in pain when electrical nerve stimulation (ENS) of most types was applied to any anatomic location of chronic musculoskeletal pain (back, knee, hip, neck) for any length of treatment. Of the 38 studies used in the analysis, 35 favored ENS over placebo. All locations of pain were included based on the rationale that "mechanism, rather than anatomic location of pain, is likely to be a critical factor for therapy." The overall design of this study used questionable methodology and the results require further evaluation before application to specific clinical practice. ([Johnson, 2007](#)) ([Novak, 2007](#)) ([Furlan, 2007](#)) 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](#))

Current Treatment Coverage Guidelines:

- *BlueCross BlueShield*: TENS is considered investigational for treatment of chronic back pain, chronic pain and post-surgical pain, but is covered for certain members based on CMS rules. ([BlueCross BlueShield, 2007](#))
- *CMS*: The use of TENS for the relief of acute post-operative pain is covered for 30 days or less (as an adjunct and/or alternative to pharmaceutical treatment). TENS is also covered as treatment for chronic intractable pain. Medicare requires a month-long trial period in order to determine if there is a significant therapeutic effect. ([Medicare, 2006](#))
- *Aetna & Humana*: consistent with the CMS Guidelines ([Aetna, 2005](#)) ([Humana, 2004](#))
- *VA*: TENS is considered equivocal when compared to other modalities. ([US Dept VA, 2001](#))
- *European Federation of Neurological Societies (EFNS)*: TENS may be better than placebo (level C) although worse than electro-acupuncture (level B); TENS is non-invasive and suitable as a preliminary or add-on therapy. ([Cruccu, 2007](#))

Criteria for the use of TENS:

Chronic intractable pain (for the conditions noted above):

- Documentation of pain of at least three months duration
- There is evidence that other appropriate pain modalities have been tried (including medication) and failed
- A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a [functional restoration](#) approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial
- Other ongoing pain treatment should also be documented during the trial period including medication usage
- A treatment plan including the specific short- and long-term goals of treatment with the TENS unit should be submitted
- A 2-lead unit is generally recommended; if a 4-lead unit is recommended, there must be documentation of why this is necessary

Form-fitting TENS device: This is only considered medically necessary when there is documentation that there is such a large area that requires stimulation that a conventional system cannot accommodate the treatment, that the patient has medical conditions (such as skin pathology) that prevents the use of the traditional system, or the TENS unit is to be used under a cast (as in treatment for disuse atrophy)

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)