

# Wren Systems

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## NOTICE OF INDEPENDENT REVIEW DECISION

**DATE OF REVIEW:** Nov/25/2010

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Purchase of a TENS unit

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

MD, Board Certified in Physical Medicine and Rehabilitation

**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)

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Official Disability Guidelines

10/25/10, 11/4/10

, Inc. 10/19/10

M.D., P.A. 6/20/08 to 11/3/10

imaging Center 8/8/07

**PATIENT CLINICAL HISTORY SUMMARY**

This is a man injured on xx/xx/xx. He developed post laminectomy syndrome. Lyrica helped his burning dysethesias. Dr. noted that he has muscle spasms with pain. Soma did not help the spasms. He previously purchased a TENS that is not currently working. Dr. wrote in his note of 10/19/10 that he had the TENS in the past, but did not describe its effectiveness until his appeal letter of November 3, 2010 "The patient has had a TENS Unit in the past, which worked wonderfully." He is currently using a borrowed TENS.

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

The request for the TENS unit was not previously accompanied by any statement by Dr. of its efficacy. But according to an appeal letter dated November 3, 2010 "The patient has had a TENS Unit in the past, which worked wonderfully." The claimant's use of a borrowed unit also demonstrates more than the one month trial that it works. The records reflect the unit is to be part of a complete treatment program rather than one single modality. The claimant is at work with "magnetized electrical equipment." The claimant has met ODG Criteria for the use

of TENS. Because this device has proven to be effective for this claimant and because this man is currently at work, the reviewer finds there is medical necessity for Purchase of a TENS unit.

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

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) TENS should be differentiated from other types of electrical stimulators. See Electrical stimulators (E-stim) for a list of alternatives.

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) 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. (Khadilkar-Cochrane, 2008) A new evidence-based review from the American Academy of Neurology concludes that TENS is not recommended for use in treating chronic low-back pain (level A, 2 class 1 studies) but adds that TENS should be considered to treat diabetic neuropathy (level B, 2 class 2 studies). In the highest-quality studies of chronic low back pain, there was no benefit of TENS compared to sham or placebo TENS. In diabetic polyneuropathy, some studies showed slight benefit. Acute low back pain not normally seen in neurologic conditions was not considered in this review. The authors also point out that absence of evidence is not evidence of absence, and that TENS has had a long-standing role in pain management, is easy to handle, has a favorable benefit-to-risk ratio, and can be discontinued easily if it is not efficacious. (Dubinsky, 2010)

#### 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. (Crucchi, 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-AMERICA COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

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)