



IRO#
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Notice of Independent Review Decision

DATE OF REVIEW: 9/11/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

IRO - RS2M unit purchase with supplies

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

This case was reviewed by a Texas licensed MD, specializing in Pain Management, nesthesiology. The physician advisor has the following additional qualifications, if applicable:

ABMS Anesthesiology: Pain Medicine, Anesthesiology

REVIEW OUTCOME:

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

Upheld

Health Care Service(s) in Dispute	CPT Codes	Date of Service(s)	Outcome of Independent Review
IRO - RS2M unit purchase with supplies	E0745	-	Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

No	Document Type	Provider or Sender	Page Count	Service Start Date	Service End Date
1	IRO Request		15	08/31/2009	
2	UR Request		3	06/19/2009	
3	UR Request		3	07/16/2009	
4	RX History		1	06/15/2009	
5	Office Visit Report		1	04/21/2009	
6	RX History		1	03/05/2009	
7	Office Visit Report		2	03/05/2009	
8	Office Visit Report		2	01/05/2009	

9	Office Visit Report		2	11/03/2008	
10	Office Visit Report	Dr.	1	07/18/2009	
11	Referral	Dr.	4	06/18/2009	
12	RX History	Dr.	1	06/04/2009	
13	Office Visit Report	Dr.	1	11/21/2008	
14	Lab Report	Dr.	3	10/29/2008	
15	Office Visit Report		2	07/09/2009	
16	Office Visit Report		2	06/04/2009	
17	Lab Report		1	11/28/2006	
18	Office Visit Report	Dr.	1	08/11/2009	
19	Op Report	Dr.	2	06/04/2008	
20	Office Visit Report		2	08/25/2009	

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a xx-year-old female with a date of injury from xx/xx/xx. The mechanism of injury was not provided. The patient has been seen by Dr. and treated for chronic pain secondary to lumbar post-laminectomy syndrome. There was an RS4i and conductive garment used and was reported to provided benefit. There was mention that it reduced the amount of opioid intake; however this is not reflected in the notes provided. The patient was also seen by a neurosurgeon, who felt the patient was not a candidate for further surgery. There were two (2) prior requests that were denied on the basis of the ODG guides. There is now a request for the purchase of an RS2i unit (TENS unit).

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

Based on the available clinical, the request for the purchase of an RS2i unit is not considered medically necessary. The ODG guides specifically do not support the use of TENS units for the chronic treatment of low back pain. There is support for short term use (1 month) provided that this is in conjunction with a functional restoration program, however, this is not the case. Based on this, the request is not supported by the ODG guides.

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

ODG:

Pain Chapter

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. High-frequency 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. ([Khadiikar-Cochrane, 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. ([Crucchu, 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)