

Case Number:	CM14-0203516		
Date Assigned:	12/16/2014	Date of Injury:	07/01/2005
Decision Date:	02/03/2015	UR Denial Date:	12/02/2014
Priority:	Standard	Application Received:	12/05/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Family Practice and is licensed to practice in Ohio. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 57-year-old female with a cumulative trauma injury with an end date of July 1, 2005. She sustained injuries to her neck, right upper extremity, and low back. In 2008 she had a cervical fusion from C3-C6. In May 2014 she had a medial branch block from C6-T1. She has tried numerous treatments including but not limited to Naprosyn, Neurontin, Opana ER, physical therapy, iontophoresis, lumbar support, massage, biofeedback, therapy, numerous medications, and a TENS unit. The TENS unit appears to have been prescribed April 14, 2014. Injured worker complains of ongoing and worsening low back pain and worsening paresthesia the right upper extremity. The diagnoses include chronic regional pain syndrome, depression, lumbar radiculopathy, peripheral neuropathy, cervical and lumbar spondylosis, chronic pain syndrome, and history of a cervical fusion. The physical exam reveals tenderness of the cervical and lumbar facet joints, tenderness of the lumbar paraspinal musculature with spasm, hyperalgesia of the dorsum of the right hand, a positive straight leg raise test on the left side with diminished sensation region of the L5 dermatome, and a positive Tinel's and Phalen's test to the right wrist. At issue is a 6 month rental of a NexWave combo stimulation unit with batteries and electrodes for 6 months. The utilization review physician did not certify this request on the basis that the original justification for a TENS unit was not satisfied and that the agreed medical examiner did not include a TENS unit as a portion of the future medical care needs according to a note from May 3, 2011.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

NexWave combo stim unit (in months) QTY: 6: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy TENS Page(s): 114-116.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS (transcutaneous electrical nerve stimulation) Page(s): 114-116.

Decision rationale: Transcutaneous electrical stimulation is 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. 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, including diabetic neuropathy and post-herpetic neuralgia. Phantom limb pain and CRPS II: Some evidence to support use. Spasticity: TENS may be a supplement to medical treatment in the management of spasticity in spinal cord injury. 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. 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. 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.- 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 chronic pain medical treatment guidelines MTUS (Effective July 18, 2009) Page 116 of 127 require a month-long trial period in order to determine if there is a significant therapeutic effect. (Medicare, 2006)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 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.In this instance, there is no documentation provided that a one month trial with the Nexwave unit occurred and/or was successful. It is unclear what the intended application site for the electrodes is as there is little or no discussion from the available record on this subject. A discussion cannot be found describing benefits from the unit in terms of pain relief, improved functionality, or reduced medication usage. Lastly, it appears that the injured worker is worsening instead of improving with regard to her right upper extremity and low back complaints. Hence, it would appear from the record that the potential sites of application and use of this unit are not deriving a benefit. Consequently, the NexWave combo stim unit (in months) QTY: 6, was not medically necessary per the referenced guidelines.

Electrodes QTY: 24: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not cite any medical evidence for its decision.

Decision rationale: Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

Batteries QTY: 24: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not cite any medical evidence for its decision.

Decision rationale: Since the primary procedure is not medically necessary, none of the associated services are medically necessary.