

Case Number:	CM14-0158791		
Date Assigned:	10/02/2014	Date of Injury:	06/02/2012
Decision Date:	10/31/2014	UR Denial Date:	09/09/2014
Priority:	Standard	Application Received:	09/29/2014

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 Physical Medicine & Rehabilitation, has a subspecialty in Pain Management and is licensed to practice in California. 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's original date of injury was June 2, 2012. The injured worker has complaints of neck pain, low back pain, right knee pain, and bilateral hip pain. The industrial diagnoses include lumbar spine spondylolisthesis, lumbar disc herniation, chronic cervical strain, and right shoulder rotator cuff syndrome, lumbar radiculopathy, left hip pain with the possibility of internal derangement, and associated anxiety and depression. The disputed requests are for a topical compounded cream and a TENS unit. A utilization review determination had noncertified these requests on the basis of the Lidocaine not being approved as part of the compounded formulation, and the patient's TENS unit not being medically necessary based on the patient's diagnoses.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac/Lidocaine cream (3%/5%) 180 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 112.

Decision rationale: Topical Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical Lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. Non-neuropathic pain: Not recommended. There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. With regards to the request for topical Lidocaine, the guidelines clearly specify that the only formulation that is susceptible for topical Lidocaine is as a patch. Given that the topical analgesics criteria also specify that if one drug or drug class of a compounded formulation is not recommended, then the entire formulation is not recommended, this request is not medically necessary.

one (1) TENS unit: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 114-117.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on Pages 114-116 specify the following regarding TENS (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 including diabetic neuropathy (Spruce, 2002) 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. A review of this injured worker's industrial diagnoses failed to reveal any of the indications above of multiple sclerosis, specificity, Phantom limb pain, or complex regional pain syndrome. By statute, the California Medical Treatment and Utilization Schedule takes precedence over other national guidelines which may have broader indications for TENS unit. Given this worker's diagnoses, TENS is not medically necessary. In this worker, there are multiple orthopedic complaints present, but no evidence of spasticity or localized neuropathic pain that is amenable to TENS treatment. Therefore, this request is not medically necessary.