MAXIMUS Federal Services

| Case Number: | CM15-0174134 | | |
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| Date Assigned: | 09/15/2015 | Date of Injury: | 01/18/2000 |
| Decision Date: | 10/15/2015 | UR Denial Date: | 09/01/2015 |
| Priority: | Standard | Application Received: | 09/03/2015 |

## 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: North Carolina
Certification(s)/Specialty: Family Practice

## 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 56-year-old male, with a reported date of injury of 01-18-2000. The diagnoses include chronic low back pain, lumbar fusion at L3-, L4-5, and L5-S1, lumbar radiculopathy, reactive anxiety due to pain, and neurogenic bladder. Treatments and evaluation to date have included Norco, Percocet, and a TENS (transcutaneous electrical nerve stimulation) unit. The diagnostic studies to date have included a urine drug screen on 06-29-2015 with consistent results; a urine drug screen on 06-24-2015; chiropractic treatment; and lumbar epidural steroid injection on 07-16-2012. The progress report dated 08-13-2015 indicates that the injured worker's most recent urine drug screen from 06-24-2015 "was consistent with Norco and Percocet use, and it did not detect any illicit drug use." The injured worker continued to have low back pain with radiation to the left side near the tailbone, and associated with pain in both legs and burning pain and numbness in both great toes. He also had numbness on the anterior and lateral right leg. It was noted that the Lidoderm patches were helpful when applied to the low back; the topical compound cream provided additional pain relief. The injured worker underwent a CT scan of the lumbar spine on 04-12-2012 which showed fusion at the L5-S1 level, no evidence of hardware complication; and multilevel lumbar spondylosis with mid central spinal stenosis at L3-4 and probably impingement of the exiting L5 nerve roots. The objective findings include moderate discomfort; independent and slowed gait; a well-healed mid line lumbar scar; moderate tenderness over the lumbar paraspinal muscles with spasms; limited lumbar spine range of motion; diminished sensation to light touch to the lateral aspect of the right lower leg; decreased extensor hallucis longus strength on the right compared to the left; and

positive right seated straight leg raise test. The treatment plan on 07-22-2015 includes the refill of Lidoderm patch, applied one to the affected area 12 hours on 12 hours off as needed for pain; and a refill for TENS patches. The treating physician requested Lidoderm patch topical cream #30 and I refill of TENS unit patches, two-month supply. On 09-01-2015, Utilization Review (UR) non-certified the request for Lidoderm patch topical cream #30 and I refill of TENS unit patches, two-month supply.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription for Lidoderm patch topical cream #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical lidocaine states: 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. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) 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. (Scudds, 1995) This medication is recommended for localized peripheral pain. The patient does have lower extremity pain, however the patient has no documented failure of all first line agents indicated for the treatment of neuropathic pain as outlined above. Therefore criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.

**1 refill TENS unit patches 2 months supply:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

**Decision rationale:** The California chronic pain medical treatment guidelines section on transcutaneous electrical nerve stimulation states: 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. This treatment option is recommended as an adjunct to a program of evidence based functional restoration. In addition there must be a 30 day trial with objective measurements of improvement. These criteria have not been met in the review of the provided clinical documentation and the request is not medically necessary.