

<b>Case Number:</b>	CM15-0132320		
<b>Date Assigned:</b>	07/20/2015	<b>Date of Injury:</b>	04/27/2011
<b>Decision Date:</b>	08/21/2015	<b>UR Denial Date:</b>	06/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/08/2015

### 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 53 year-old female, who sustained an industrial injury on 4/27/2011. She reported a fall with injury to the left knee. Diagnoses include left knee pain; status post left knee surgery x 2; low back pain and lumbar facet pain. Treatments to date include medication therapy and physical therapy. Currently, he/she complained of left knee pain and associated with weakness and giving out. On 3/12/15, the physical examination documented an antalgic gait, tenderness and decreased strength. The plan of care included Lidocaine gel 2%; and TENS unit trial for one month.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lidocaine gel 2%:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical lidocaine Page(s): 111-112.

**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. There is no documentation of failure of first line neuropathic pain medications. Therefore, criteria as set forth by the California MTUS as outlined above have not been met and the request is not medically necessary.

**TENS unit trial x1 month:** Overturned

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

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

**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 and it is recommended for a one-month trial to document subjective and objective gains from the treatment. Therefore, the request is medically necessary.