

<b>Case Number:</b>	CM15-0081801		
<b>Date Assigned:</b>	05/04/2015	<b>Date of Injury:</b>	09/28/2007
<b>Decision Date:</b>	06/03/2015	<b>UR Denial Date:</b>	04/21/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/28/2015

### 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: California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 69 year old female, who sustained an industrial injury on 9/28/07. Initial complaints are not noted. The injured worker was diagnosed as having radiculopathy; chronic pain syndrome; low back pain. Treatment to date has included physical therapy (helpful); Home Exercise Program (helpful); acupuncture (not helpful); TENS unit (lessens pain and improves function); and medications (helpful). The PR-2 dated 3/10/15 indicated the injured worker complained of daytime pain that was relatively well controlled but nighttime pain that has been increasingly difficult to tolerate. She had not received any Lidoderm patches and was using hot oil at home to topically rub on her back. She noted the Lidoderm patch helped her sleep and had been using it for the last 5 years, but it was denied two months ago. She was unable to sleep because of the pain as well as a headache. She states the pain was so severe she had difficulty walking and her tolerance for walking was quite short as she was afraid of falling. Pain levels on this date were 8-9/10 (her pain level was 5-6/10 in the past when she used the Lidoderm patches and the Voltaren gel). She had no falls recently but felt very weak. The pain was worse with hip flexion and extension. She was wondering if a walker would be a good idea. She noted tingling down the right leg in the L5 distribution and bilateral finger tips. She had been taking Advil though it upsets her stomach. The injured worker had completed 8 of 8 physical therapy sessions, uses a TENS unit and needed a refill on medications. The only diagnostic reviewed was an EMG from 2010 that showed no evidence of motor lumbar radiculopathy. A physical examination was completed and revealed range of motion of the lumbar spine exam showed severely limited flexion and "0" extension. The provider noted tenderness at L1-T12. Neurologic examination

noted muscle strength tests are limited due to pain with pain in all leg movement. X-rays of the thoracic, lumbar and sacral spine are requested to rule out compression fracture and this was authorized. The provider's treatment plan also included these requests: Transcutaneous electrical nerve stimulation (TENS) unit, electrodes and batteries 3 month supply; Lidoderm 5% patch (700mg/patch), 3 patches to back daily as needed for pain, #90 with 2 refills; Voltaren 1% gel, #1 tube.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Transcutaneous electrical nerve stimulation (TENS) unit, electrodes and batteries 3 month supply:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment, Chapter 12 Low Back Complaints Page(s): 48, 300, Chronic Pain Treatment Guidelines Transcutaneous electrotherapy Page(s): 114-27.

**Decision rationale:** Transcutaneous electrical nerve stimulation (TENS) is the use of electric current produced by a device placed on the skin to stimulate the nerves and which can result in lowering acute or chronic pain. There is a lot of conflicting evidence for use of TENS as well as many other physical modalities making it difficult to understand if TENS therapy is actually helping a patient or not. According to ACOEM guidelines there is not enough science-based evidence to support using TENS in the treatment of chronic pain. On the other hand, many sources, including the Chronic Pain Medical Treatment Guidelines (CPMTG), recommend at least a one month trial of TENS to see if there is functional improvement by using this modality. However, this trial is limited to patients with either neuropathic pain, chronic regional pain syndrome, phantom limb pain, spasticity, multiple sclerosis or in the first 30 days after surgery and the unit must be used in conjunction with other treatment modalities in an overall approach to functional restoration. A meta-analysis in 2007 suggested effectiveness of this modality for chronic musculoskeletal pain but random controlled studies are needed to verify this effectiveness. The MTUS lists specific criteria for use of this treatment. The patient has been using this device for over 3 months. Although the MTUS criteria have not been well documented for this patient in prior notes a recent note (5/19/15) does document the effectiveness of this device in improving function and decreasing pain. Medical necessity for continued use of this device has been established. The request is medically necessary.

**Lidoderm 5% patch (700mg/patch), 3 patches to back daily as needed for pain, #90 with 2 refills:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm, Topical analgesics Page(s): 56-7, 111-13.

**Decision rationale:** Lidoderm (lidocaine) patch is an anesthetic product formulated for topical use. The use of topical agents to control pain is considered by the MTUS to be an option although it is considered largely experimental, as there is little to no research to support their use. Topical lidocaine in the form of Lidoderm is recommended in the MTUS only for treatment of neuropathic pain. Other topical forms of this medication are not recommended and use of this medication for non-neuropathic pain is also not recommended. Additionally, use of Lidoderm is recommended only after trial of first-line therapy with medications such as tricyclic antidepressants, SRNI antidepressants or antiepileptic drugs (AED). This patient has neuropathic pain and is presently taking an AED medication yet still has significant pain. Prior use of Lidoderm patches has decreased her pain and improved her function. Continued use of Lidoderm patches is indicated. Medical necessity has been established. The request is medically necessary.

**Voltaren 1% gel, #1 tube:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain - Voltaren Gel (Diclofenac).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 49, Chronic Pain Treatment Guidelines Anti-inflammatory medications, NSAIDs (non-steroidal anti-inflammatory drugs); Topical Analgesics Page(s): 22, 67-73, 111-13. Decision based on Non-MTUS Citation Klinge SA, Sawyer GA. Effectiveness and safety of topical versus oral non-steroidal anti-inflammatory drugs: a comprehensive review. Phys Sportsmed. 2013 May;41(2):64-74.

**Decision rationale:** Diclofenac Gel (Voltaren Gel) is a non-steroidal anti-inflammatory (NSAIDs) medication formulated for topical use. The systemic form of this medication is indicated for treatment of mild to moderate pain. Topical NSAIDs have been effective in short-term use trials for chronic musculoskeletal pain but long-term use has not been adequately studied. In general, the use of topical agents to control pain is considered an option by the MTUS although it is considered largely experimental, as there is little to no research to support their use. Topical NSAIDs are primarily recommended for treatment of osteoarthritis and tendonitis. Head-to-head studies of oral NSAIDs with topical NSAIDs suggest topical preparations should be considered comparable to oral NSAIDs and are associated with fewer serious adverse events, specifically gastrointestinal reactions. This patient has been using Voltaren Gel for over 3 months with documentation of its effectiveness in decreasing the patient's pain. This patient's trials of oral NSAIDs has been associated with development of dyspepsia. The provider notes that some of the patient's pain is due to osteoarthritis and has ordered x-rays to document this disease process. Considering all the above information, continued use of his medication is a reasonable therapeutic option. Medical necessity has been established. The request is medically necessary.