

<b>Case Number:</b>	CM15-0207780		
<b>Date Assigned:</b>	10/26/2015	<b>Date of Injury:</b>	10/05/2004
<b>Decision Date:</b>	12/09/2015	<b>UR Denial Date:</b>	10/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/21/2015

### 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: Physical Medicine & Rehabilitation

### 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 male, who sustained an industrial-work injury on 10-5-04. A review of the medical records indicates that the injured worker is undergoing treatment for chronic low back pain status post fusion 9-16-09 and 9-2-15, lumbar radiculopathy, and status post spinal cord stimulator implant. Medical records dated 10-7-15 indicate that the injured worker no longer has pain and numbness to the right leg. He reports 80 percent improvement in low back pain. The physician indicates that the Gabapentin helps alleviate the neuropathic pain and the Lidoderm patches provide additional pain relief. The physical exam reveals that he is in mild discomfort and gait is slowed using a single point cane for assistance. He is wearing a lumbar brace. The lower extremity sensation to light touch and strength is within normal limits bilaterally. Treatment to date has included pain medication Norco, Oxy IR, Gabapentin, Alprazolam, Amitriptyline, Aspirin, Cymbalta, Percocet, Lidoderm patch since at least 4-30-15, Topical Ketoprofen since at least 2-3-15, Dilaudid, status post spinal cord stimulator implant, psyche care, lumbar fusion, epidural steroid injection (ESI) and other modalities. The physician indicates that he gets gastrointestinal upset with Non-steroidal anti-inflammatory drugs. The treating physician indicates that the urine drug test result dated 7-12-15 and 8-12-15 was consistent with the medication prescribed. The requested services included Lidocaine patch #30 and Topical Ketoprofen. The original Utilization review dated 10-14-15 non-certified the request for Lidocaine patch #30 and Topical Ketoprofen.

### IMR ISSUES, DECISIONS AND RATIONALES

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

### **Lidocaine patch #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch).

**Decision rationale:** Based on the 8/12/15 progress report provided by the treating physician, this patient presents with sharp low back pain with radiation down the right leg to his toes, with numbness/tingling, with pain rated 7-8/10 on VAS. The treater has asked for Lidocaine patch #30 on 8/12/15. The request for authorization was not included in provided reports. The patient had a prior spinal fusion at L5-S1 of unspecified date per 4/24/15 report. The patient has GI upset from prior use of NSAIDs, and avoids acetaminophen as he takes aspirin on daily basis per 8/12/15 report. The patient uses the spinal cord stimulator on a regular basis per 6/17/15 report. The spinal cord stimulator was placed in 2012 per 4/24/15 report. The patient's work status is not included in the provided documentation. MTUS Chronic Pain Medical Treatment Guidelines 2009, page 57, Lidoderm (Lidocaine patch) section states, "topical lidocaine may be 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)." MTUS Page 112 also states, "Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain." ODG guidelines, chapter Pain (Chronic) under Lidoderm (Lidocaine patch) specifies that Lidoderm patches are indicated as a trial if there is "evidence of localized pain that is consistent with a neuropathic etiology." ODG further requires documentation of the area for treatment, trial of a short-term use with outcome documenting pain and function. In this case, Lidoderm patch was first prescribed in progress report dated 4/2/15 and is mentioned in subsequent reports dated 5/20/15, 6/17/15, and 8/12/15. The patient reports better pain relief from increased dose of Oxy IR, and the Lidoderm patches are stated to provide "additional pain relief" per 6/17/15 report. However, the treater does not indicate where the patch is to be used, other than instructions to "apply to affected area 12 hours on 12 hours off PRN pain." MTUS, however, supports the use of Lidoderm patches only for peripheral neuropathic pain and not for back pain. Hence, the request is not medically necessary.

### **Topical Ketoprofen: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

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

**Decision rationale:** Based on the 8/12/15 progress report provided by the treating physician, this patient presents with sharp low back pain with radiation down the right leg to his toes, with numbness/tingling, with pain rated 7-8/10 on VAS. The treater has asked for topical ketoprofen on 8/12/15. The request for authorization was not included in provided reports. The patient had a prior spinal fusion at L5-S1 of unspecified date per 4/24/15 report. The patient has GI upset from prior use of NSAIDs, and avoids acetaminophen as he takes aspirin on daily basis per 8/12/15 report. The patient uses the spinal cord stimulator on a regular basis per 6/17/15 report. The spinal cord stimulator was placed in 2012 per 4/24/15 report. The patient's work status is not included in the provided documentation. MTUS, Topical Analgesics section, page 111-113 has the following: 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.

Topical Analgesics: Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. MTUS further states, "Non FDA-approved agents:

Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. 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.

Gabapentin: Not recommended. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." MTUS Guidelines, Medications for Chronic Pain section, pg. 60, 61 states: "Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)." The patient has been using topical Ketoprofen as early as 2/3/15 report, and is currently using it per requesting 8/12/15 report. The treater documents that the patient has had GI upset due to previous NSAID use, and that the patient is not currently taking oral NSAIDs. However, the patient has not indicated where this topical is applied and with what efficacy per review of reports dated 2/3/15 to 8/12/15. MTUS page 60 states that a record of pain and function are required when medications are prescribed for chronic pain. Furthermore, MTUS page 111 states that if one of the compounded topical product is not recommended, then the entire product is not. In this case, the requested topical compound contains Ketoprofen, which is not supported for topical use in lotion form, per MTUS. This request is not in accordance with guideline indications. Therefore, the request is not medically necessary.