

<b>Case Number:</b>	CM15-0093865		
<b>Date Assigned:</b>	05/20/2015	<b>Date of Injury:</b>	05/23/2013
<b>Decision Date:</b>	06/26/2015	<b>UR Denial Date:</b>	05/05/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/15/2015

### 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: Internal 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 64-year-old male, who sustained an industrial injury on 05/23/2013. According to a progress report dated 04/06/2015, the injured worker complained of low back pain with lower extremity symptoms, left greater than right. Pain was rated 7 on a scale of 1-10. Medication history included a history of narcotic addiction. Medications tried and failed included nonsteroidal anti-inflammatory drugs. Topical nonsteroidal anti-inflammatory drugs facilitated a 5-point diminution in axial low back pain with improved range of motion 30% in all planes and a significant increase in tolerance to standing and walking. Objective findings included tenderness to the lumbar spine. Lumbar range of motion demonstrated 35 degrees with flexion, 25 degrees with extension, 20 degrees left and right lateral tilt and 25 degrees left and right rotation. He had difficulty arising from a seated position. Gait was slightly antalgic. Straight leg raise was positive bilaterally. Diagnoses included multiple levels of foraminal stenosis, greatest at L5 with radiculopathy. Treatment to date has included medications, epidural steroid injections, TENs unit and home exercise. Treatment plan included L5-S1 decompression, postoperative physical therapy and Ketoprofen 10% in base, 300 grams. The provider noted that the injured worker had failed first and second line nonsteroidal anti-inflammatory drug options due to adverse gastrointestinal effects/ineffectiveness. Currently under review is the request for Ketoprofen 10 percent in base 300 grams with 3 refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 10% in base 300 grams, with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain, as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) indicates that nonsteroidal anti-inflammatory drugs (NSAID) can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. Therefore, they should be used only acutely. The patient sustained an injury on 05/23/13. The patient was diagnosed with multiple levels foraminal stenosis greatest with radiculopathy. Prior treatments included physical therapy and medication, which both failed. The patient was using Lidoderm patches. The patient received epidural injections, which provided only temporary relief. Magnetic resonance imaging MRI of the lumbar spine dated 01/16/15 documented moderately severe narrowing particularly at the left L5-S1. Neurodiagnostic studies dated 01/20/15 documented no evidence of significant radiculopathy. ACOEM indicates that nonsteroidal anti-inflammatory drugs (NSAID) should be used only acutely. The patient's occupational injuries are chronic. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Long-term NSAID use is not recommended by MTUS. The use of the topical NSAID Ketoprofen 10% quantity 300 grams with 3 refills is not supported by MTUS guidelines. Therefore, the request for topical Ketoprofen is not medically necessary.