

<b>Case Number:</b>	CM15-0197311		
<b>Date Assigned:</b>	10/12/2015	<b>Date of Injury:</b>	05/03/2000
<b>Decision Date:</b>	11/24/2015	<b>UR Denial Date:</b>	09/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/07/2015

### 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 51-year-old male who sustained an industrial injury on 5-3-2000. Diagnoses have included spondylosis, cervical without myelopathy, chronic pain due to trauma, derangement of posterior horn of medial meniscus, cervical radiculopathy, myalgia and myositis, insomnia due to medical condition. Documented treatment includes medication, including Gabapentin, Amitriptyline, and Suboxone. Medication was reported to help bring pain from 10 out of 10 to a 7. He rated the pain interrupted his quality of life as 8 out of 10 with 10 being "unable to carry on any activities." On 9-16-2015, the injured worker presented with complaint of severe, worsening, constant pain in his neck, both shoulders and arms, and he stated the pain was radiating to the upper extremities, low back, and both lower extremities. Pain was characterized as aching, burning, dull, piercing, sharp, shooting, stabbing, throbbing and deep. He also reported some numbness. Activity was reported as aggravating his pain while medication provided relief. The treating physician's plan of care includes a new 30-day supply of Pennsaid Solution 2 percent, which was denied on 9-30-2015.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**30 Days Supply of Pennsaid Solution 2% 112ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Online Edition, 2015, Pain (Chronic), Pennsaid.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Pennsaid (Diflofenac Sodium Topical Solution) Section.

**Decision rationale:** Per the MTUS Guidelines, the use of topical analgesics is recommended as an option for some agents. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Per the ODG, Pennsaid is not recommended as a first-line treatment. Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, and after considering the increased risk profile with diclofenac, including topical formulations. In studies, Pennsaid was as effective as oral diclofenac, but was much better tolerated. FDA approved Pennsaid Topical Solution in 2009 for the treatment of the signs and symptoms of osteoarthritis of the knee, and the FDA requires a Risk Evaluation and Mitigation Strategy (REMS) from the manufacturer to ensure that the benefits of this drug outweigh its risks. In this case, there is no evidence that the injured worker has failed with or is unable to tolerate oral NSAIDs, therefore, the request for 30 days supply of Pennsaid solution 2% 112ml is not medically necessary.