

<b>Case Number:</b>	CM14-0029118		
<b>Date Assigned:</b>	06/20/2014	<b>Date of Injury:</b>	01/08/2009
<b>Decision Date:</b>	08/22/2014	<b>UR Denial Date:</b>	02/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/07/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 66-year-old female who reported an injury on 01/08/2009. The mechanism of injury was the injured worker was walking and stubbed her right foot on concrete and fell and hit her right knee and hit her head above her right eyebrow. The medication history in early 2013 included gabapentin 300 mg, citalopram 400 mg, zolpidem 5 mg, and Theramine. Prior treatments included physical therapy and medications. Additional treatments included conservative treatment and biofeedback. The injured worker's medication history included gabapentin and cyclobenzaprine, tramadol and flurbiprofen topicals as of 11/2013. The documentation of 03/18/2014 revealed the injured worker had complaints of neck pain right posterior neck and right shoulder pain. The injured worker complained of right headaches and right low back pain as well as bilateral knee pain and bilateral ankle pain, left shoulder pain, and face pain. The injured worker had decreased range of motion. The diagnoses included cervical-brachial syndrome, shoulder tenosynovitis in the right, tenosynovitis in the left ankle, headaches, probable post traumatic insomnia, lumbar neuritis, and postoperative right knee and left knee pain, and was postoperative in the bilateral knees. The treatment included gabapentin, cyclobenzaprine transdermal, tramadol 20% transdermal, and flurbiprofen 20% transdermal.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen compound cream 150 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, page 72, Topical analgesics page 111 Page(s): 72, 111.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The clinical documentation submitted for review failed to provide the efficacy of the requested medication. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The clinical documentation indicated the injured worker had been utilizing the medication since at least 11/2013. The request as submitted failed to indicate the frequency and the strength of the requested medication. Additionally, the clinical documentation indicated the injured worker was taking an oral NSAID. There was a lack of documentation indicating a necessity for both an oral and topical form of NSAIDs. Given the above, the request for flurbiprofen compound cream 150 gm is not medically necessary.

**Gabapentin compound cream 120 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin, page 113, Topical Analgesics, page 111 Page(s): 113, 111.

**Decision rationale:** The California MTUS indicated that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended. There is no peer-reviewed literature to support use. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication since at least 11/2013. There was a lack of documented efficacy for the requested medication. There was a lack of documentation of functional benefit.

The request as submitted failed to indicate the frequency and the strength of the requested medication. Given the above, the request for gabapentin compound cream 120 gm is not medically necessary.

**Tramadol compound cream 150 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, page 82, Topical Analgesics, page 111 Page(s): 82, 111. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA.gov.

**Decision rationale:** FDA.gov The Expert Reviewer's decision rationale: The California MTUS indicated that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. The clinical documentation submitted for review indicated the injured worker had been utilizing the topical medication since at least 11/2013. Additionally, the injured worker was noted to be utilizing tramadol ER 150 mg. There was a lack of documentation indicating a necessity for both a topical and oral form of tramadol. The request as submitted failed to indicate the frequency and the strength of the requested medication. Given the above, the request for tramadol compound cream 150 gm is not medically necessary.