

<b>Case Number:</b>	CM14-0082579		
<b>Date Assigned:</b>	07/21/2014	<b>Date of Injury:</b>	07/05/2012
<b>Decision Date:</b>	09/19/2014	<b>UR Denial Date:</b>	05/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/04/2014

### 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 Occupational Medicine 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 patient is an 80-year-old male who has submitted a claim for head contusion, post-traumatic headache, head injury, lumbar musculoligamentous injury, lumbar myospasm, and lumbar radiculopathy, associated with an industrial injury date of July 5, 2012. Medical records from 2013 through 2014 were reviewed. The latest progress report, dated 04/11/2014, showed intermittent headaches and occasional jaw pain. The patient has dizzy spells. The patient complained of frequent, severe, dull, achy, sharp low back pain and stiffness, associated with repetitive sitting, standing, walking, and climbing stairs. Physical examination revealed slow and guarded gait which favored the right lower extremity. There was restricted range of motion of the lumbar spine. There was tenderness and spasms on bilateral gluteus and lumbar paravertebral muscles. Kemp's test was positive bilaterally. Sitting straight leg raise test was positive on the right. Treatment to date has included acupuncture and topical creams since 2013. Utilization review from 05/07/2014 denied the request for the purchase of capsaicin 0.025%, flurbiprofen 15%, tramadol 15%, menthol 2%, camphor 2%, 240 gram; flurbiprofen 25%, cyclobenzaprine 0.2%, 240 gram; gabapentin 10%, lidocaine 5%, tramadol 15%, 240 gram; diclofenac 25%, tramadol 15%, 240 gram because the guideline criteria have not been met as there were insufficient large-scale, randomized, controlled references showing the safety and efficacy of the requested compound prescription in this patient's clinical scenario. It was not clear that the patient was intolerant of oral medications. The compounded substances were composed of drugs that have, in many instances, no FDA approval for a topical form, have no identified clinical application in topical form or both.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Capsaicin 0.025%, Flurbiprofen 15%, Tramadol 15%, Menthol 2%, Camphor 2%  
240GM: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 117.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 28, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Topical Salicylates.

**Decision rationale:** As noted on pages 111-113 in the CA MTUS Chronic Pain Medical Treatment Guidelines, there is little to no research as for the use of flurbiprofen in compounded products. The topical formulation of Tramadol does not show consistent efficacy. According to page 28 of the CA MTUS Chronic Pain Medical Treatment Guidelines, topical capsaicin has moderate to poor efficacy but may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. Regarding the menthol component, CA MTUS does not cite specific provisions, but the ODG Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. The guidelines do not address camphor. In this case, compounded products were prescribed for relief of pain. However, there is no discussion concerning the need for five different topical medications. In addition, certain components of this compound, i.e., flurbiprofen and tramadol, are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for capsaicin 0.025%, flurbiprofen 15%, tramadol 15%, menthol 2%, camphor 2%, 240 grams is not medically necessary.

**Flurbiprofen 25%, Cyclobenzaprine 0.2% 240GM: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 117.

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

**Decision rationale:** As noted on pages 111-113 in the CA MTUS Chronic Pain Medical Treatment Guidelines, there is little to no research as for the use of flurbiprofen in compounded products. The use of cyclobenzaprine as a topical muscle relaxant is not recommended. In this case, compounded products were prescribed for relief of pain. However, there is no discussion concerning the need for two different topical medications. In addition, certain components of this compound, i.e., flurbiprofen and cyclobenzaprine, are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for flurbiprofen 25%, cyclobenzaprine 0.2%, 240 grams is not medically necessary.

**Gabapentin 10%, Lidocaine 5%, Tramadol 15% 240GM: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 117.

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

**Decision rationale:** As noted on pages 111-113 in the CA MTUS Chronic Pain Medical Treatment Guidelines, topical Gabapentin is not recommended and has no peer-reviewed literature to support its use. Topical formulations of lidocaine and Prilocaine (whether creams, lotions or gels) are not indicated for neuropathic or non-neuropathic pain complaints. Guidelines also state that no other commercially approved topical formulations of lidocaine, other than lidocaine dermal patch (Lidoderm), are indicated for neuropathic pain. The topical formulation of tramadol does not show consistent efficacy. In this case, compounded products were prescribed for relief of pain. However, there is no discussion concerning the need for three different topical medications. In addition, certain components of this compound, i.e., gabapentin, lidocaine and tramadol, are not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for gabapentin 10%, lidocaine 5%, tramadol 15%, 240 grams is not medically necessary.

**Diclofenac 25%, Tramadol 15% 240GM: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 117.

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

**Decision rationale:** As noted on pages 111-113 in the CA MTUS Chronic Pain Medical Treatment Guidelines, the topical formulation of tramadol does not show consistent efficacy. Diclofenac is an FDA-approved topical agent. In this case, compounded products were prescribed for relief of pain. However, there is no discussion concerning the need for two different topical medications. In addition, certain component of this compound, i.e., tramadol, is not recommended for topical use. The guidelines state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for diclofenac 25%, tramadol 15%, 240 grams is not medically necessary.