

<b>Case Number:</b>	CM13-0043052		
<b>Date Assigned:</b>	12/27/2013	<b>Date of Injury:</b>	01/14/2011
<b>Decision Date:</b>	04/28/2014	<b>UR Denial Date:</b>	10/11/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/31/2013

### 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 employee of [REDACTED] who has submitted a claim for a neck sprain associated with an industrial injury from January 14, 2011. Treatment to date has included oral, topical and parenteral analgesics, exercise education program, cervical and lumbar epidural steroid injection, acupuncture and cervical spine surgery. Utilization review from October 11, 2013 denied the request for topical compound medications containing Ketoprofen/lidocaine/capsaicin/Tramadol and flur/Cyclobenzaprine/capsaicin/lidocaine as these contain drugs that are not recommended for topical application. Medical records from February 2013 to January 2014 were reviewed showing the patient complaining of persistent neck pain, chronic headaches radiating to the upper extremities with numbness and tingling and low back pain aggravated by motion. A progress report dated April 23, 2013 showed cervical spine tenderness of the paravertebral and upper trapezial muscles with spasm on physical examination. There is moderate reduction in cervical spine motion due to pain. No changes in sensory and motor examination were reported. Naproxen taken every 12 hours as needed for pain would temporarily relieve his headaches allowing him to perform his activities of daily living. The patient was prescribed with naproxen and Tramadol for pain, Medrox pain relief ointment for muscle aches, Cyclobenzaprine for muscle spasms, sumatriptan for headache, ondansetron for nausea and omeprazole for acid reflux. Patient reported compliance with prescribed medications. Cervical spine surgery was also recommended. Average pain level of the patient was 8/10 with medications and 10/10 without medications as stated in a progress report on May 21, 2013. The patient also reports limitation in areas of activities of daily living such as self-care/hygiene, activity, ambulation, hand function, sleep and sex. In July 16, 2013 progress report, decrease in patient pain level was noted, averaging 6/10 with medications and 9/10 without medications. In patient had receive cervical epidural steroid injection on September 2013 and a positive response

was noted from the patient however objective findings status quo and patient's pain level was back to 8/10 with medications and 10/10 without medications. The patient underwent cervical spine surgery on December 18, 2013. In a progress report dated January 28, 2014, physical examination findings still noted cervical spine tenderness with moderate reduction in cervical motion due to pain. Pain levels are now 9/10 with or without medications. Toradol injection was given.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **COMPOUNDED TOPICAL CONTAINING KETOPROFEN/LIDOCAINE/CAPSAICIN/TRAMADOL: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS, COMPOUNDED.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MTUS CHRONIC PAIN MEDICAL TREATMENT GUIDELINES Page(s): 111-113.

**Decision rationale:** According to CA MTUS Chronic Pain Medical Treatment Guidelines pages 111-113, ketoprofen is not currently FDA approved for a topical application due to extremely high incidence of photocontact dermatitis. Topical capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Lidocaine topical is only approved as a dermal patch formulation. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. It is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Tramadol is indicated for moderate to severe pain. In addition, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, the requested topical medication contains ketoprofen and lidocaine which are not FDA approved. There is no discussion concerning the need for variance from the guidelines. The request for Ketoprofen/lidocaine/capsaicin/Tramadol is therefore not medically necessary.

#### **COMPOUNDED TOPICAL CONTAINING FLUR/CYCLOBENZAPRINE/CAPSAICIN/LIDOCAINE: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation TOPICAL ANALGESICS, COMPOUNDED.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation MTUS CHRONIC PAIN MEDICAL TREATMENT GUIDELINES.

**Decision rationale:** Page 111-113 of MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Compounded Flurbiprofen and NSAIDs in general do not show consistent efficacy and are not FDA approved. Cyclobenzaprine is a skeletal muscle relaxant and

there is no evidence for use of any muscle relaxant as a topical product. Topical capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Lidocaine topical is only approved as a dermal patch formulation. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. It is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, there is no objective evidence showing that the patient has failed a trial for oral pain medication, therefore all the drug classes in the requested topical compounded product, including capsaicin, is not recommended. There is no discussion concerning the need for variance from the guidelines. The request for flur/Cyclobenzaprine/capsaicin/lidocaine is therefore not medically necessary.