

<b>Case Number:</b>	CM13-0067414		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	12/22/2009
<b>Decision Date:</b>	05/28/2014	<b>UR Denial Date:</b>	12/09/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/16/2013

### 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 Internal 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:

Primary treating physician's evaluation dated 06/29/2013 was provided by [REDACTED]. The patient sustained an injury while performing his usual and customary duties as a sanitation worker for the school district. He was stripping and cleaning classrooms. A co-worker lost control of a buffer machine and struck the patient. The patient has a history of high cholesterol and hypertension. The patient is taking amlodipine and atorvastatin. He is also taking over-the-counter aspirin. The patient's father is deceased who had diabetes, heart disease, and stroke. Treatment recommendations: transdermal compounded medications and/or medications to decrease pain/inflammation: capsaicin 0.025%, Flurbiprofen 30%, methyl salicylate 4% 240 gm., and Flurbiprofen 20%, tramadol 20% 240 gm., and Medrox patch 30 gm. topical cream, Flexeril, Ultracet. Date of injury was 12-22-2009. PR-2 dated 08-13-2013 documented no prescription medications. PR-2 Treating Physician's Progress Report 11-05-2013 was provided by [REDACTED]. Subjective: 55 year old male with history of hypertension, here to follow-up on low back pain, left hip. 8-9/10 constant. Symptoms same - medications help little more. Left leg spasms/tingling. Objective: antalgic gait, ambulates with cane, left lower extremity strength 3/5, right lower extremity strength 5/5, left hip tender, lumbosacral tender. Diagnosis: lumbar intervertebral disc (IVD) syndrome with radiculopathy, cervical IVD syndrome with radiculopathy, thoracic IVD syndrome, left hip severe osteoarthritis, left hip avascular necrosis. Treatment plan included chiropractic, acupuncture, ESWT, LINT, TENS; referral to Internal Medicine for hypertension as soon as possible; Capsaicin 0.025%, Flurbiprofen 20%, Tramadol 10%, Menthol 2%, Camphor 2% topical; Flurbiprofen 25%, Lidocaine 10% topical. Utilization review dated 12-09-2013 recommended that the requested items be denied: Item 1: 240 gram Compound Capsaicin 0.025%, Flurbiprofen 20%, Tramadol 10%, Menthol 2%, Camphor 2% Item 2: 240 gram Compound Flurbiprofen 25%, Lidocaine 10%.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUND (CAPSAICIN 0.025%, FLURBIPROFEN 20%, TRAMADOL 10%, MENTHOL 2%, CAMPHOR 2% #240GM): Upheld**

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

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

**Decision rationale:** Primary treating physician's report 06/29/2013 documented that patient has hypertension. "The patient has a history of high cholesterol and hypertension. The patient is taking amlodipine and atorvastatin. He is also taking over-the-counter aspirin. The patient's father is deceased who had diabetes, heart disease, and stroke." Medical records dated 06-29-2013, 08-13-2013, 11-05-2013 did not document blood pressure measurements. FDA Prescribing Information for Flurbiprofen presents warnings of cardiovascular risk: Possible increased risk of serious (sometimes fatal) cardiovascular thrombotic events (e.g., MI, stroke). Individuals with cardiovascular disease or risk factors for cardiovascular disease may be at increased risk. Hypertension and worsening of preexisting hypertension reported; either event may contribute to the increased incidence of cardiovascular events. Use with caution in patients with hypertension; monitor BP. Patient has hypertension, hyperlipidemia, and a family history of heart disease and stroke. Patient has been prescribed amlodipine and atorvastatin. Blood pressure has not been monitored. Given the patient's cardiovascular risk factors and FDA's warnings, Flurbiprofen is not recommended. Medical treatment utilization schedule (MTUS) Chronic Pain Medical Treatment Guidelines states that Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Medical records does not document the patient's response or tolerance to other treatments. Therefore, per MTUS guidelines, Capsaicin is not recommended. Medical treatment utilization schedule (MTUS) Chronic Pain Medical Treatment Guidelines states that 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. Since Flurbiprofen and Capsaicin are not recommended, the compounded product is not recommended. Therefore, the request for Compound Capsaicin 0.025%, Flurbiprofen 20%, Tramadol 10%, Menthol 2%, Camphor 2% 240 gram is Not medically necessary.

**REFILLS FOR COMPOUND (FLURBIPROFEN 25%, LIDOCAINE 10%) 240 GRAM: Upheld**

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

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

**Decision rationale:** Primary treating physician's report 06/29/2013 documented that patient has hypertension. "The patient has a history of high cholesterol and hypertension. The patient is taking amlodipine and atorvastatin. He is also taking over-the-counter aspirin. The patient's father is deceased who had diabetes, heart disease, and stroke." Medical records dated 06-29-2013, 08-13-2013, 11-05-2013 did not document blood pressure measurements. FDA Prescribing Information for Flurbiprofen presents warnings of cardiovascular risk: Possible increased risk of serious (sometimes fatal) cardiovascular thrombotic events (e.g., MI, stroke). Individuals with cardiovascular disease or risk factors for cardiovascular disease may be at increased risk. Hypertension and worsening of preexisting hypertension reported; either event may contribute to the increased incidence of cardiovascular events. Use with caution in patients with hypertension; monitor BP. Patient has hypertension, hyperlipidemia, and a family history of heart disease and stroke. Patient has been prescribed amlodipine and atorvastatin. Blood pressure has not been monitored. Given the patient's cardiovascular risk factors and FDA's warnings, Flurbiprofen is not recommended. Medical treatment utilization schedule (MTUS) Chronic Pain Medical Treatment Guidelines states that Lidocaine recommended for localized neuropathic peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Medical records does not document a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Therefore, per MTUS guidelines, Lidocaine is not recommended. Medical treatment utilization schedule (MTUS) Chronic Pain Medical Treatment Guidelines states that 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. Since Flurbiprofen and Lidocaine are not recommended, the compounded product is not recommended. Therefore, the request for compound Flurbiprofen 25%, Lidocaine 10% 240 gram is Not medically necessary.