

<b>Case Number:</b>	CM15-0125994		
<b>Date Assigned:</b>	07/10/2015	<b>Date of Injury:</b>	12/29/2011
<b>Decision Date:</b>	09/11/2015	<b>UR Denial Date:</b>	05/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/30/2015

### 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: New York

Certification(s)/Specialty: Anesthesiology

### 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 57-year-old male, with a reported date of injury of 12/29/2011. The mechanism of injury was moving and lifting sheets of plywood from a stage. The injured worker's symptoms at the time of the injury included sharp pain in the low back. The diagnoses include lumbar spine degenerative disc disease, facet arthropathy, right more than left radiculopathy; and lumbar spine sprain/strain. Treatments and evaluation to date have included chiropractic treatment, which helped mildly and briefly; physical therapy; acupuncture; oral medications; lumbar facet blocks; bilateral radiofrequency ablation; and home exercise program. The diagnostic studies to date have included an x-ray of the lumbar spine on 07/03/2012 which showed mild spondylosis at L1-L2 and mild degenerative disc disease at L5-S1; an MRI of the lumbar spine on 01/24/2014, 10/29/2012, and 02/23/2012; and an anatomical impairment measurement of the lumbar spine on 05/05/2015 with normal findings. The progress report dated 05/05/2015 indicates that the injured worker had lumbar spine pain, which was rated 6 out of 10. There was no radiculitis/radiculopathy. It was noted that the injured worker had increased low back pain with squatting down. There was documentation that the injured worker's functional change was slower than expected. His previous and current functionality was the same. The objective findings include tenderness of the lumbar spine and lumbar-sacral spine; positive bilateral straight leg raise test; and decreased lumbar range of motion with pain. The injured worker's work status was noted as return to modified duties on 06/05/2015. The treating physician prescribed two compounded medication creams, with one refill, to be applied twice a

day. The treating physician requested Flurla/Menthol/Capsaicin/Camphor cream and Cyclobenzaprine/Ultram cream.

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

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

**Medication-Compound Cream: Flurla/Menthol/Capsaicin/Camphor with one refill:**

Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 298, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The guidelines note that these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In this case, the topical analgesic compound requested contains: Flurbi/Menthol/Capsaicin/Camphor. The treating physician's request did not include the concentration, quantity, or site of application. The requested compound medication contains Flurbiprofen, a non-steroid anti-inflammatory drug (NSAID), indicated for use for osteoarthritis and tendinitis, particularly in the knee, elbow, or other joints that are amenable to topical treatment, not recommended for neuropathic pain. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). The Official Disability Guidelines (ODG) notes that currently the only available FDA-approved topical NSAID is diclofenac. The guidelines note that Capsaicin is only recommended when other, conventional treatments have failed. A new alert from the FDA warns that topical over-the-counter (OTC) pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns. The MTUS and Official ODG do not discuss the use of Camphor in topical analgesics. Flurbiprofen is not FDA approved for topical application, therefore the compound is not recommended. Therefore, based on the guidelines, the request for Flurbi/Menthol/Capsaicin/Camphor cream, with 1 refill, is not medically necessary.

**Medication-Compound Cream: Cyclobenzaprine/Ultram, with one refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 298, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." It was noted that the injured worker was prescribed Ativan for anxiety and Wellbutrin for depression. There was no documentation that the antidepressant was prescribed for neuropathic pain. The guidelines state that they are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." The compounded medication is a combination of Cyclobenzaprine and Ultram. Cyclobenzaprine is a muscle relaxant and Ultram is an opioid. The MTUS states that there is no evidence for the use of any other muscle relaxant as a topical product. According to the guidelines, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The MTUS/ACOEM Guidelines indicate that non-prescription pain killers will provide sufficient pain relief for most patients with acute and sub acute low back symptoms. If the treatment response is inadequate, prescribed medications or physical methods can be added. The treating physician's request did not include the concentration, quantity, or site of application. As such, the requested prescription is not sufficient and is not medically necessary.