

<b>Case Number:</b>	CM14-0064244		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	08/05/2013
<b>Decision Date:</b>	09/15/2014	<b>UR Denial Date:</b>	04/28/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/07/2014

### 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 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 a 34-year-old male who has submitted a claim for lumbosacral neuritis associated with an industrial injury date of August 5, 2013. Medical records from 2013 to 2014 were reviewed. The patient complained of low back, bilateral knee and right ankle pain. Physical examination showed tenderness over the L4-L5, L5-S1 facet area bilaterally; positive facet loading in the lower lumbar region; tenderness of the right medial and lateral knee, and peripatellar area of the left knee; positive McMurray's bilaterally; limitation of motion of the bilateral knees secondary to pain; and tenderness over the right medial ankle and dorsum of the right foot. The diagnoses were lumbar spine sprain/strain; lumbar radiculopathy; multilevel lumbar spine disc protrusions; axial lower back pain; lumbar facet arthropathy, L4-L5, L5-S1 bilaterally; left knee tricompartmental osteoarthritis and possible medial meniscal tear; right knee pain with lateral tibial plateau fracture; osteochondritis dissecans calcaneal spurring; and posterior tibialis tenosynovitis. Treatment to date has included oral and topical analgesics, muscle relaxants, lumbar medial branch nerve block, physical therapy, and acupuncture. Utilization review from April 28, 2014 denied the request for 240gm Capsaicin 0.025%, Flurbiprofen 15%, Tramadol 15%, Menthol 2%, Camphor 2%; 240gm Cyclobenzaprine 2%, Flurbiprofen 20%; and 240 gm Amitriptyline 4%, Dextromethorphan 10%, Tramadol 20%. This compound medicine request is a health care treatment for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but that is not yet broadly accepted as the prevailing standard of care based on main-stream, peer-reviewed studies of this particular formulation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

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

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

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Regarding menthol and capsaicin components, California MTUS does not cite specific provisions, but the Official Disability Guidelines Pain Chapter states that the FDA has issued an alert in 2012 indicating that topical OTC pain relievers that contain Capsaicin, Menthol and Salicylate may in rare instances cause serious burns. Regarding the Flurbiprofen component, topical NSAID formulation is only supported for Diclofenac in the California MTUS. Regarding the Tramadol component, guidelines do not support the use of Tramadol in topical formulation. In addition, guideline states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, medical records did not show failure or intolerance to oral formulations. Moreover, all of the components of the requested compounded medication are not recommended for topical use. The medical necessity has not been established. There was no compelling rationale concerning the need for variance from the guideline. Therefore, the request for 240gm Capsaicin 0.025%, Flurbiprofen 15%, Tramadol 15%, Menthol 2%, Camphor 2% is not medically necessary.

**240gm Cyclobenzaprine 2%, Flurbiprofen 20%:** Upheld

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

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Regarding the Flurbiprofen component, topical NSAID formulation is only supported for Diclofenac in the California MTUS. Also, there is no evidence to support the use of topical Cyclobenzaprine, and the addition of Cyclobenzaprine to other agents is not recommended. Guideline states that any compounded product that contains at least one drug (or drug class) that is not recommended is

not recommended. In this case, medical records did not show failure or intolerance to oral formulations. Moreover, all of the components of the requested compounded medication are not recommended for topical use. The medical necessity has not been established. There was no compelling rationale concerning the need for variance from the guideline. Therefore, the request for 240gm Cyclobenzaprine 2%, Flurbiprofen 20% is not medically necessary.

**240 gm Amitriptyline 4%, Dextromethorphan 10%, Tramadol 20%: Upheld**

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

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Regarding the amitriptyline component, guidelines recommend its use with Ketamine for treatment of chemotherapy-induced peripheral neuropathy. Dextromethorphan is not addressed in the guidelines. Regarding the Tramadol component, guidelines do not support the use of Tramadol in topical formulation. In addition, guideline states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, medical records did not show failure or intolerance to oral formulations. Tramadol is not recommended for topical use. Furthermore, there was no evidence of chemotherapy-induced peripheral neuropathy to warrant the use of topical Amitriptyline. The medical necessity has not been established. There was no compelling rationale concerning the need for variance from the guideline. Therefore, the request for 240 gm Amitriptyline 4%, Dextromethorphan 10%, Tramadol 20% is not medically necessary.