

<b>Case Number:</b>	CM14-0172268		
<b>Date Assigned:</b>	10/23/2014	<b>Date of Injury:</b>	04/26/2012
<b>Decision Date:</b>	12/02/2014	<b>UR Denial Date:</b>	10/06/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/17/2014

### 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 Family 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:

This is a 51-year-old male patient who reported an industrial injury on 4/26/2012, over two and a half years ago, attributed to the performance of her usual and customary job tasks. The patient complained of lower back pain and bilateral knee pain. The patient received medications, physical therapy, and activity modifications. The medical records were reviewed. MRI of the lumbar spine demonstrated evidence of a disc protrusion L5-S1 a 3 mm, L4-L5 4 mm disc protrusion, and L2-L3 4 mm disc protrusion. The MRI of the knee demonstrated a medial meniscus tear. The objective findings on examination included a reported positive straight leg raise to the left lower extremity; effusion and tenderness of the bilateral knees. The treatment plan included 12 sessions of chiropractic care directed to the lumbar spine and topical compounded analgesics x2.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen/Cyclobenzaprine/Lidocaine 10 percent/3 percent/5 percent 120g #1:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-114.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 128, Chronic Pain Treatment Guidelines Anti-Inflammatory Medications, Muscle Relaxants, Topical Analgesics Page(s): 22, 67-68, 63, 111. Decision based on Non-

MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Cyclobenzaprine; Muscle Relaxants; Topical Analgesics; Topical Analgesics Compounded

**Decision rationale:** The prescription for the topical analgesic Ketoprofen/Cyclobenzaprine/Lidocaine 10 percent/3 percent/5 percent 120g #1 is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is clinical documentation submitted to demonstrate the use of the topical gels for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the Official Disability Guidelines, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with any assessment of functional improvement. The patient is stated to have reduced pain with the topical creams, however, there is no functional assessment, and no quantitative decrease in pain documented. Evidence-based guidelines report that compounded drugs are not evaluated for safety or efficacy by the federal FDA. According to the FDA, compounded drugs carry significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed topical analgesic is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The use of topical compounded analgesics is documented to have efficacy for only 2-4 weeks subsequent to injury, and thereafter, is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs or the prescribed analgesics. There is no demonstrated medical necessity for topical NSAIDs for chronic pain for a prolonged period of time. The request for the topical compounded analgesics Ketoprofen/Cyclobenzaprine/Lidocaine 10 percent/3 percent/5 percent 120g #1 is not medically necessary for the treatment of the patient for the diagnosis of the chronic pain. The use of the topical gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels on areas that are not precise. The volume applied and the times per day that the gels are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of gels to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The use of the topical compounded analgesic Ketoprofen/Cyclobenzaprine/Lidocaine 10 percent/3 percent/5 percent 120g #1 not supported by the applicable evidence-based guidelines as cited above. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical analgesic medication for the treatment of the industrial injury. The prescription of Ketoprofen/Cyclobenzaprine/Lidocaine 10 percent/3 percent/5 percent 120g #1 is not recommended by the California MTUS; ACOEM guidelines,

and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The prescription for the topical compounded analgesic Ketoprofen/Cyclobenzaprine/Lidocaine 10 percent/3 percent/5 percent 120g #1 is not medically necessary for the treatment of the patient's chronic pain complaints.

**Flurbiprofen/Capsaicin/Camphor 10/0.25/2 percent/1 percent 120g #1:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-114.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 128, Chronic Pain Treatment Guidelines Anti-Inflammatory Medications, Topical Analgesics Page(s): 22, 67-68, 63, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Cyclobenzaprine; Muscle Relaxants; Topical Analgesics; Topical Analgesics Compounded

**Decision rationale:** The prescription for the topical analgesic Flurbiprofen/Capsaicin/Camphor 10/0.25/2 percent/1 percent 120g #1 is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is clinical documentation submitted to demonstrate the use of the topical gels for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the Official Disability Guidelines, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with any assessment of functional improvement. The patient is stated to have reduced pain with the topical creams, however, there is no functional assessment, and no quantitative decrease in pain documented. Evidence-based guidelines report that compounded drugs are not evaluated for safety or efficacy by the federal FDA. According to the FDA, compounded drugs carry significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed topical analgesic is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The use of topical compounded analgesics is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs or the prescribed analgesics. There is no demonstrated medical necessity for topical NSAIDs for chronic pain for a prolonged period of time. The request for the topical compounded analgesics Flurbiprofen/capsaicin/camphor

10/0.25/2 percent/1 percent 120g #1 is not medically necessary for the treatment of the patient for the diagnosis of the chronic pain. The use of the topical gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels on areas that are not precise. The volume applied and the times per day that the gels are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of gels to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The use of the topical compounded analgesic Flurbiprofen/Capsaicin/Camphor 10/0.25/2 percent/1 percent 120g #1 not supported by the applicable evidence-based guidelines as cited above. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical analgesic medication for the treatment of the industrial injury. The prescription of Flurbiprofen/Capsaicin/Camphor 10/0.25/2 percent/1 percent 120g #1 is not recommended by the California MTUS; ACOEM guidelines, and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The prescription for the topical compounded analgesic Flurbiprofen/Capsaicin/Camphor 10/0.25/2 percent/1 percent 120g #1 is not medically necessary for the treatment of the patient's chronic pain complaints.