

Case Number:	CM14-0159672		
Date Assigned:	10/03/2014	Date of Injury:	05/08/2014
Decision Date:	12/03/2014	UR Denial Date:	09/12/2014
Priority:	Standard	Application Received:	09/29/2014

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 37-year-old female patient who reported an industrial injury on 5/8/2014, over six (6) months ago, attributed to the performance of her usual and customary job duties reported as left hand pain subsequent to picking broccoli. The patient complained of pain to the neck radiating to the left shoulder, left elbow, left wrist, and hand with numbness and tingling. The objective findings on examination included decreased left grip strength; pain with motion of the cervical spine; positive Spurling's sign; positive foraminal compression; normal left shoulder motion; painful motion of the left elbow and wrist; tenderness to the left palm; and negative Tinel's sign. The patient was under the care of pain management for the diagnoses of rule out cervical disc protrusion; rule out cervical radiculitis versus radiculopathy; left shoulder pain; left elbow dysfunction; and left hand pain. The patient was treated for left hand pain with Tylenol 3; naproxen; Flexeril; omeprazole; 12 sessions of physical therapy; and a topical compounded analgesic Capsaicin 0.025%, Flurbiprofen 20%, and Tramadol 180gm.

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, 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines anti-inflammatory medications; muscle relaxants; topical analgesics; topical Capsaicin Page(s):. 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 compounded analgesic Capsaicin 0.025%, Flurbiprofen 20%, Tramadol, 180gm. x1 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 ODG, 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 and no 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 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 Capsaicin 0.025%, Flurbiprofen 20%, Tramadol 180gm. x1 is 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 for the topical

compounded analgesic Capsaicin 0.025%, Flurbiprofen 20%, Tramadol 180gm. is not medically necessary for the treatment of the patient's chronic pain complaints. The prescription of Capsaicin 0.025%, Flurbiprofen 20%, Tramadol 180gm. is not recommended by the CA 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 objective findings in the clinical documentation provided do not support the continued prescription of Capsaicin 0.025%, Flurbiprofen 20%, Tramadol 180gm. x1 for the treatment of chronic pain. The request is not medically necessary.