

Case Number:	CM14-0041032		
Date Assigned:	06/27/2014	Date of Injury:	06/24/2012
Decision Date:	01/05/2015	UR Denial Date:	03/14/2014
Priority:	Standard	Application Received:	04/07/2014

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 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 27-year-old female patient who reported an industrial injury to the feet, back, and arm on 6/24/2012, 2 years ago, attributed to the performance of her usual and customary job tasks reported as throwing trash bags into the dumpster. The patient was diagnosed with cervical radiculopathy, right shoulder arthropathy; and lumbar radiculopathy. The patient complains of lower back pain that radiates to the lower extremities; neck pain that radiates to the upper extremities; and right shoulder pain. Heat, cold, acupuncture, ESWT (extracorporeal shock wave therapy), massage, traction, ultrasound, exercise, TENS unit, chiropractic care/CMT, Anaprox, Prilosec, Orphenadrine, and Medrox. The MRI of the lumbar spine documented evidence of multilevel disc protrusions, thickening of the ligamentum flavum, boney hypertrophy of articular facets, and moderate decrease in the AP sagittal diameter. The MRI of the cervical spine documented moderate disc dehiscence. The MRI of the right shoulder documented evidence of tendinosis of the rotator cuff with a tear and moderate impingement syndrome. The patient was prescribed topical compounded analgesics x2.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound cream, Ketoprofen/Lidocaine 20%/10%: Upheld

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

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 Page(s): 22, 67-68, 63, 1. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), pain chapter 2008, pages 128 and on the Official Disability Guidelines (ODG) pain chapter, cyclobenzaprine; muscle relaxants; topical analgesics; topical analgesics compounded.

Decision rationale: 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 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 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 20%/Lidocaine 10% 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 Ketoprofen 20%/Lidocaine 10% is not medically necessary for the treatment of the patient's chronic pain complaints. The prescription of Ketoprofen 20%/Lidocaine 10% 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 that "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 Ketoprofen 20%/Lidocaine 10% for the treatment of chronic pain. There is no demonstrated medical necessity for the topical compounded cream Ketoprofen 20%/Lidocaine 10%.

Compound cream, Gabapentin/Ketoprofen/Lidocaine: Upheld

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

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 Page(s): 22, 67-68, 63, 111. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), pain chapter 2008, pages 128 and on the Official Disability Guidelines (ODG) pain chapter, cyclobenzaprine; muscle relaxants; topical analgesics; topical analgesics compounded.

Decision rationale: The prescription for the topical compounded analgesic Gabapentin/Ketoprofen/Lidocaine 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 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 Gabapentin/Ketoprofen/Lidocaine 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 Gabapentin/Ketoprofen/Lidocaine 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 Gabapentin/Ketoprofen/Lidocaine is not medically necessary for the treatment of the patient's chronic pain complaints. The prescription of Gabapentin/Ketoprofen/Lidocaine 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 that "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 the topical compounded analgesic Gabapentin/Ketoprofen/Lidocaine for the treatment of chronic pain.