MAXIMUS Federal Services

Case Number:	CM14-0160130		
Date Assigned:	10/03/2014	Date of Injury:	06/10/2013
Decision Date:	12/03/2014	UR Denial Date:	09/19/2014
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 55-year-old male patient who reported an industrial injury on 8/23/2013, 15 months ago attributed to the performance of his usual and customary job tasks reported as the cumulative trauma due to playing a drum. The patient reported injuries to the neck, lower back, bilateral shoulders, left elbow, bilateral hands, and left leg. The patient also included injuries to his circulatory system, gastrointestinal system, nervous system, psych, and hearing loss. The patient is noted to be not working. The patient complained of pain to the cited body parts. The patient was diagnosed with an unspecified hearing loss; displacement of a cervical intervertebral disc without myelopathy; and displacement lumbar intervertebral disc without myelopathy. The patient is status post cervical anterior disc decompression and fusion at C6-C7 performed during October 2013. The patient has been treated with corticosteroid injections for the neck and epidural steroid injections for the lumbar spine. The patient also received physical therapy; activity modification; Xanax; sleeping pills; and NSAIDs. On 8/14/2014, the patient was dispensed Anexsia-Hydrocodone-APAP 7.5/325 mg #60; Diclofenac/Lidocaine cream 3%/5% 180 g. and Kera-Tek analgesic gel.

IMR ISSUES, DECISIONS AND RATIONALES

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

Anexsia-Hydrocodone 7.5/325mg QTY: 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74--97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter-opioids

Decision rationale: Evidence-based guidelines recommend short-term use of opioids for the management of chronic nonmalignant moderate to severe pain. Long-term use is not recommended for nonmalignant pain due to addiction, dependency, intolerance, abuse, misuse, and/or side effects. Ongoing opioid management criteria are required for long-term use with evidence of reduce pain and improve function as compared to baseline measurements or a return to work. The prescription for Anexsia-Hydrocodone-APAP 7.5/325 mg #60 for short acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the neck, back, and UEs/LEs for the date of injury 15 months ago attributed to the effects of his job as a drummer and moving heavy equipment associated with playing music. The objective findings on examination do not support the medical necessity for the dispensed opioid analgesics. The patient is being prescribed opioids for reported chronic pain, which is inconsistent with the recommendations of the CA MTUS. There is no objective evidence provided to support the continued prescription of opioid analgesics for the cited diagnoses and effects of the industrial claim. The patient should be titrated down and off the prescribed Hydrocodone. The patient is 15 months s/p DOI with reported continued issues. There is no demonstrated medical necessity for the continuation of opioids for the effects of the industrial injury.The chronic use of Hydrocodone-APAP is not recommended by the CA MTUS; the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic back, neck or extremity pain. The prescription of opiates on a continued long-term basis is inconsistent with the CA MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic back pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain. The current prescription of opioid analgesics is inconsistent with evidence-based guidelines. The prescription of opiates on a continued long-term basis is inconsistent with the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain issues.Evidence-based guidelines necessitate documentation that the patient has signed an appropriate pain contract, functional expectations have been agreed to by the clinician, and the patient, pain medications will be provided by one physician only, and the patient agrees to use only those medications recommended or agreed to by the clinician to support the medical necessity of treatment with opioids.The ACOEM Guidelines updated chapter on chronic pain states, "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (70 days). This leads to a concern about confounding issues; such as, tolerance, opioid-induced hyperalgesia, long-range adverse effects, such as, hypogonadism and/or opioid abuse, and the influence of placebo

as a variable for treatment effect."ACOEM guidelines state that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms; they should be used only if needed for severe pain and only for a short time. The long-term use of opioid medications may be considered in the treatment of chronic musculoskeletal pain, If: The patient has signed an appropriate pain contract; Functional expectations have been agreed to by the clinician and the patient; Pain medications will be provided by one physician only; The patient agrees to use only those medications recommended or agreed to by the clinician. ACOEM also note, "Pain medications are typically not useful in the subacute and chronic phases and have been shown to be the most important factor impeding recovery of function." There is no clinical documentation by with objective findings on examination to support the medical necessity of Hydrocodone-APAP for this long period of time or to support ongoing functional improvement. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with the prescribed Hydrocodone-APAP. There is no demonstrated medical necessity for the prescribed Opioids. The continued prescription for Anexsia-Hydrocodone-APAP 10/325 mg #60 as dispensed is not demonstrated to be medically necessary.

Diclofenac/Lidocaine cream 3%/5% 180gm: Upheld

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

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 Diclofenac 3%/Lidocaine 5% cream 180 grams 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 Diclofenac 3%/Lidocaine 5% cream 180 grams is not medically necessary for the treatment of the patient for the diagnosis of the chronic pain. The use of the topical gels/creams does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels or creams 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 Diclofenac 3%/Lidocaine 5% cream 180 grams 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 Diclofenac 3%/Lidocaine 5% cream 180 grams is not medically necessary for the treatment of the patient's chronic pain complaints. The prescription of Diclofenac 3%/Lidocaine 5% cream 180 grams 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 Diclofenac 3%/Lidocaine 5% cream 180 grams as prescribed and dispensed on 8/14/2014 for the treatment of chronic pain. Therefore, this request is not medically necessary.

Kera-Tek Analgesic Gel: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, NSAIDs Page(s): 111-113; 22, 67-68, 71. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2ndEdition, (2004) Chapter 6, pages 114-15 and Official Disability Guidelines (ODG); Pain Chapter topical analgesics; NSAIDs.

Decision rationale: The prescription for Kera-Tek analgesic gel is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient as opposed to the readily available salicylate preparations available over-the-counter. It is not clear that the topical salicylate gel is 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.The request for Kera-Tek analgesic gel 4 oz. is not medically necessary for the treatment of the patient for the reported chronic pain issues. There are many alternatives available OTC for the prescribed topical analgesics or topical salicylates.The use of the topical creams or gels do not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams 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 Kera-Tek analgesic gel not supported by the applicable ODG guidelines as cited below. 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 compounded medication for the treatment of the industrial injury. The prescription for Kera-Tek analgesic gel is not medically necessary for the treatment of the patient's pain complaints. The prescription of Kera-Tek analgesic gel is not recommended by the CA MTUS 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 for the treatment of chronic pain over the available OTC topical salicylate preparations. There is no demonstrated medical necessity for the 8/14/2014 dispensed Kera-Tek analgesic gel.