

Case Number:	CM14-0168829		
Date Assigned:	10/16/2014	Date of Injury:	07/15/2009
Decision Date:	11/26/2014	UR Denial Date:	09/19/2014
Priority:	Standard	Application Received:	10/13/2014

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 57-year-old male patient who reported an industrial injury on 7/15/2009, over five (5) years ago, attributed to the performance of his usual and customary job tasks. The patient complained of persistent bilateral knee pain. The patient was noted to have the underlying comorbidity of diabetes mellitus. The patient was noted to have had an arthroscopy with meniscectomy to the left knee on 3/4/2010; manipulation under anesthesia on 4/5 2010; left knee arthroscopic debridement meniscectomy on 9/9/2010, and a left total knee replacement on 11/26/2012. The patient reported pain levels that allowed him to move around within his house for activities however, he could not get out of bed without medications. The objective findings on examination included range of motion right knee was flexion 150 an extension was 180; anterior knee was swollen; negative McMurray's sign; Lachman test and drawer test was negative; incision line was healing well; range of motion was 70% of normal was partially restricted due to pain; diffuse bilateral knee numbness. The patient was diagnosed with bilateral knee pain; internal knee derangement; bilateral and osteoarthritis of the knees. The treatment plan included Norco 2.5 mg TID #90 with three (3) refills; morphine sulfate sustained-release 30 mg 1-2 per day #60; ketoprofen cream 20% 120 mg #2; and Mediderm patches with lidocaine #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

MSSR 30 MG 1-2/D #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-306. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chapter 6 pages 114-116. Official Disability Guidelines (ODG) pain chapter opioids

Decision rationale: The prescription for Morphine Sulfate SR 30 mg #60 for long acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the bilateral knees s/p TKA for the date of injury five (5) years ago. The objective findings on examination do not support the medical necessity for continued opioid analgesics. The patient is being prescribed opioids for OA pain to the knees, 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 Morphine Sulfate Sustained release. The patient is five (5) years 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 Morphine Sulfate 30 mg #60 is not recommended by the CA MTUS; the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic knee 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 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 state, "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 notes, "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 Morphine Sulfate SR 30 mg #60 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 Morphine Sulfate. There is no demonstrated medical necessity for the prescribed Opioids. The continued prescription for Morphine Sulfate SR 30 mg #60 is not demonstrated to be medically necessary.

Ketoprofen Cream 20 Percent 120 Mg #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, NSAIDs Page(s): 111-113, 22, 67-68, 71. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 6 pages 114-15. Official Disability Guidelines (ODG) Pain Chapter topical analgesics; NSAIDs.

Decision rationale: The topical NSAID, ketoprofen 20% cream 120 mg #2, is not medically necessary in addition to prescribed oral NSAIDs. The patient has been prescribed topical ketoprofen 20% cream for chronic pain. The patient has received topical NSAID cream for a prolonged period of time exceeding the time period recommended by evidence-based guidelines. There is no demonstrated medical necessity for both an oral NSAID and a topical NSAID. There is no provided subjective or 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 CA MTUS, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no documented functional improvement by the provider attributed to the topical NSAID. The use of topical NSAIDs 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. The patient was prescribed an oral opioids and topical NSAID concurrently. The use of the topical creams/gels does 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 prolonged use of topical ketoprofen 20% cream 120 mg with refill x2 not supported by the applicable evidence-based

guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be medically necessary. The prescribed topical ketoprofen 20% cream is not demonstrated to be medically necessary.

Mediderm Patch with Lidocaine #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48, Chronic Pain Treatment Guidelines anti-inflammatory medications, chronic pain chapter's, topical analgesics Page(s): 67-68, 111-1. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter medications for chronic pain; topical analgesics

Decision rationale: The prescription of topical Mediderm/Lidocaine patches #30 with refill x1 was not demonstrated to be medically necessary and no objective evidence to support the medical necessity of the prescribed topical Mediderm/lidocaine for the cited diagnoses. The CA MTUS does not recommend the use of Mediderm/lidocaine patches for pain control, as the patches are only FDA approved for the treatment of neuropathic pain attributed to post-herpetic neuralgia. The patient is being treated with Mediderm/lidocaine patches for chronic knee pain due to OA. There is no medical necessity for the use of the Mediderm/Lidocaine patches for the objective findings documented on examination. The request for authorization of the Mediderm/Lidocaine patches is not supported with objective evidence and is not recommended as a first line treatment for the treatment of chronic shoulder pain. There is no objective evidence that the Mediderm/Lidocaine patches are more effective than the many available alternatives for the treatment of chronic pain. There is no objective evidence to support the use of Mediderm/Lidocaine patches for the stated symptoms, as there are available alternatives. There is no objective evidence to support the use of topical lidocaine for the treatment of the documented diagnoses. The applicable evidence based guidelines state that more research is required prior to endorsing the use of Mediderm/Lidocaine patches for the treatment of chronic pain. The prescription of Mediderm/Lidocaine patches is FDA approved only for post herpetic neuralgia and is not to be used as a first line treatment. The provider provides no rationale for the use of the dispensed/prescribed Mediderm/Lidocaine patches over the readily available medical alternatives. The prescription of the Mediderm/Lidocaine patches is inconsistent with evidence-based guidelines. There are no prescribed antidepressants or gabapentin to support the medical necessity of Mediderm/Lidocaine topical patches. Evidence-based guidelines necessitate documentation of localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED, such as, gabapentin or Lyrica) to support the medical necessity of Mediderm/Lidocaine patch. The patient is not taking Neurontin, thus Mediderm/Lidocaine is not appropriate for the treatment of this patient. There is no objective evidence to support the use of Mediderm/Lidocaine patches for the continuous and daily treatment of chronic back pain. There is no current clinical documentation that indicates that the patient has a localized area of neuropathic pain for which this medication would be medically necessary. There is no demonstrated medical necessity for Mediderm/Lidocaine patches or topical lidocaine ointment to treat the effects of the industrial injury. Topical lidocaine may be

recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED, such as, gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. Additionally, ODG states that topical lidocaine 5% patch/ointment has been approved by the FDA for post-herpetic neuralgia, and is used off-label for diabetic neuropathy and other neuropathic pain. It has been shown to be useful in treating various chronic neuropathic pain conditions in open-label trials. (Argoff, 2006) (ODG, Pain Chapter). There is no demonstrated medical necessity for the prescribed Mediderm/Lidocaine patches #30.

Norco 2.5 #90 Refills 3: Upheld

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

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: The prescription for Hydrocodone-APAP (Norco) 2.5/325 mg #90 refill x3 for short acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the knee due to OA of the knee and s/p TKA. The objective findings on examination do not support the medical necessity for continued opioid analgesics. The patient is being prescribed opioids for chronic knee pain s/p arthroscopy and TKA, 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 five (5) years 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/Norco is not recommended by the CA MTUS; the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic knee pain. There is no demonstrated sustained functional improvement from the prescribed opioids. 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 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 state, "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 notes, "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 Norco 2.5/325 mg #90 refill x3 is not demonstrated to be medically necessary.