

Case Number:	CM14-0049826		
Date Assigned:	07/07/2014	Date of Injury:	03/10/2006
Decision Date:	09/12/2014	UR Denial Date:	03/18/2014
Priority:	Standard	Application Received:	04/17/2014

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 66 year old male with a reported industrial injury on 3/10/2006, over 8 years ago, attributed to the performance of his customary job tasks as a shuttle driver. The patient was being treated for chronic neck and back pain. The orthopedic objective findings on examination were limited to TTP to the lumbar paraspinal muscles; limited lumbar spine ROM; and reported decreased sensation to the L5 dermatome. The diagnosis was spinal stenosis-lumbar s/p discectomy 2/22/2007; multilevel cervical disc desiccation and bulging with stenosis; depression; anxiety; and hypertension.

IMR ISSUES, DECISIONS AND RATIONALES

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

Intramuscular Injection of Toradol: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines; FDA (<http://www.drugs.com/pro/ketorolac-injection.html>).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 22; 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--NSAIDs; Ketorolac--Toradol.

Decision rationale: The IM injection of Toradol for pain was provided to give pain relief; however, the patient was previously prescribed a significant polypharmacy of oral and topical medications. The patient is 8 years s/p DOI and there is no medical necessity for the provision of IM Toradol in the office setting in addition to the prescribed medications. There is no demonstrated medical necessity for the IM injection of a NSAID in addition to the prescribed analgesics. The patient should be taking oral NSAIDs and there is no medical necessity for an IM injection of an NSAID for the reported flare up. The provision of Toradol IM was directed to chronic back pain in addition to the prescribed polypharmacy. There is no medical necessity for the provision of IM Toradol in the outpatient treatment setting for the cited diagnosis of chronic low back pain. There is no demonstrated medical necessity for the IM delivery of NSAIDs versus the oral route for the treatment of this patient. The patient was treated for chronic pain issues and the office setting injection was inconsistent with the recommendations of the ODG.

Soma 350mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines antispasticity/antispasmodic drugs Page(s): 66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--muscle relaxants and Carisoprodol.

Decision rationale: The patient is prescribed Carisoprodol/SOMA 350 mg #60 on a routine basis for the treatment of chronic pain and is not directed to muscle spasms on a prn basis. The CA MTUS does not recommend the prescription of Carisoprodol. There is no medical necessity for the prescribed Soma 350 mg #60 for chronic pain or muscle spasms as it is not recommended by evidence based guidelines. The prescription of Carisoprodol is not recommended by the CA MTUS for the treatment of injured workers. The prescription of CARISOPRODOL as a muscle relaxant is not demonstrated to be medically necessary for the treatment of the chronic back pain on a routine basis. The patient has been prescribed CARISOPRODOL on a routine basis for muscle spasms. There is no demonstrated medical necessity for the daily prescription of CARISOPRODOL as a muscle relaxer on a daily basis for chronic pain. The prescription of CARISOPRODOL for use of a muscle relaxant for cited chronic pain is inconsistent with the recommendations of the CA MTUS, the ACOEM Guidelines and the Official Disability Guidelines. The use of alternative muscle relaxants was recommended by the CA MTUS and the Official Disability Guidelines for the short term treatment of chronic pain with muscle spasms; however muscle relaxants when used are for short term use for acute pain and are not demonstrated to be effective in the treatment of chronic pain. The use of Carisoprodol is associated with abuse and significant side effects related to the psychotropic properties of the medication. The centrally acting effects are not limited to muscle relaxation. The prescription of CARISOPRODOL as a muscle relaxant is not recommended as others muscle relaxants without psychotropic effects are readily available. There is no medical necessity for CARISOPRODOL 350 mg #60. There are clearly no recommendations for the prescribed combination of Valium and Carisoprodol due to the psychotropic effects. The California MTUS guidelines state that

CARISOPRODOL is not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate a schedule for controlled substance. It has been suggested that the main effect is due to generalize sedation and treatment of anxiety. Abuses been noted for sedative and relaxant effects. In regular abusers, the main concern is for the accumulation of meprobamate. Carisoprodol abuses also been noted in order to augment or alter effects of other drugs. This includes the following increasing sedation of benzodiazepines or alcohol; used to prevent side effects of cocaine; use with tramadol to ghost relaxation and euphoria; as a combination with hydrocodone as an effective some abuses claim is similar to heroin referred to as a Las Vegas cocktail; and as a combination with codeine referred to as Carisoprodol Coma. There is no documented functional improvement with the use of the prescribed Carisoprodol. The use of CARISOPRODOL/SOMA is not recommended due to the well known psychotropic properties. Therefore this medication should be discontinued.

Norco 10/325mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

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 provider has not establish functional improvement as a result of the current regimen of Norco 10/325 mg #90 directed to mechanical back pain. As noted by evidence based guidelines, opiates may be continued if the patient has returned to work and has improved functioning and pain. Additionally, there is no indication of an improvement in pain levels or functionality to substantiate ongoing utilization of opiate medication. Long term use of opiates is not supported by current evidence based guidelines. ODG states: "Routine long-term opioid therapy is not recommended, and ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support its use." The patient has been taking opiate medication on a long-term basis, which is not consistent with evidence-based guidelines. The prescription for Norco 10/325 mg #90 for short acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the back for the date of injury 8 years ago. The patient is diagnosed with low back pain due to Lumbar spine DDD s/p discectomy. The objective findings on examination do not support the clinical diagnoses. The patient is being prescribed opioids for chronic back 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 of the prescribed Norco. The chronic use of Norco is not recommended by the CA MTUS; the ACOEM Guidelines or the Official Disability Guidelines for the long term treatment of chronic back 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 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 and eye 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 that "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." Evidence based guidelines recommend: Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. The ODG states that 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. (Ballantyne, 2006) (Furlan, 2006) Long-

term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis), (Kalso, 2004). There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-Annals, 2007) (ODG, Pain Chapter). There is no clinical documentation by the requesting provider with objective findings on examination to support the medical necessity of Norco for this long period of time 8 years s/p DOI. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with the prescribed Norco. There is no demonstrated medical necessity for the prescribed Opioids. The patient should have been weaned down and discontinued from the prescribed hydrocodone by this time.

Voltaren Cream #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

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.

Decision rationale: The topical NSAID, Voltaren gel, is not medically necessary in addition to prescribed oral NSAIDs. The patient has been prescribed topical Voltaren gel in addition to oral Naproxen. The patient has received topical NSAID gels 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 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 Voltaren cream 1% 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 Voltaren topical cream is not demonstrated be medically necessary.