

Case Number:	CM15-0189998		
Date Assigned:	10/02/2015	Date of Injury:	07/09/2003
Decision Date:	11/09/2015	UR Denial Date:	09/17/2015
Priority:	Standard	Application Received:	09/28/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: North Carolina

Certification(s)/Specialty: Family Practice

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 69 year old female, who sustained an industrial injury on 7-9-2003. The medical records indicate that the injured worker is undergoing treatment for chronic pain syndrome, cervical post-laminectomy syndrome, degeneration of lumbar intervertebral disc, and shoulder joint pain. According to the progress report dated 9-9-2015, the injured worker presented with complaints of muscle aches, joint pain, and sleep disturbances. On a subjective pain scale, she rates her pain 2 out of 10 with medications and 10 out of 10 without. The treating physician states that the medications are helping. He notes the addition of Methadone is helping a lot in conjunction with Norco. The physical examination of the cervical spine reveals pain with motion, tenderness over the bilateral paracervical, trapezius, and rhomboid muscles, trapezius trigger point pain, and decreased sensation in C6, C7, and C8. The current medications are Baclofen, Diazepam, Hydrocodone-Acetaminophen, Lyrica, Methadone (since at least 7-22-2015), Omeprazole, Zolpidem, and Voltaren gel (since at least 2-21-2015). Per notes, the medication allows her to go to the grocery store, do light housework, and use her left arm. Previous diagnostic studies were not specified. Treatments to date include medication management, trigger point injections, and surgical intervention. Work status is described as permanent and stationary. The original utilization review (9-17-2015) partially approved a request for Methadone #15 (original request was for #30). The request for Methadone #30 and Voltaren 1% topical gel was non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Methadone 5mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Methadone.

Decision rationale: The California chronic pain medical treatment guidelines section on methadone states: Methadone Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it. (Clinical Pharmacology, 2008) Steps for prescribing methadone: (1) Basic rules- Weigh the risks and benefits before prescribing methadone.- Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction.- Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments. (2) Know the information that is vital to give the patient:- Don't be tempted to take more methadone than prescribed if you are not getting pain relief. This can lead to a dangerous build-up that can cause death.- All changes in methadone dose should be made by your treating practitioner.- Methadone can make your breath slow down, or actually stop.- Methadone can slow down your heartbeat and you might not be able to detect this.- If you feel like you are having an irregular heartbeat, dizziness, light-headedness or fainting, call your doctor or clinic immediately. (FDA, 2006) (3) Be familiar with the current SAMHSA health advisory on methadone - The medication has become more accessible to unauthorized users.- It can accumulate in potentially harmful doses (especially during the first few days of treatment.- There has been a rise in Methadone-associated mortality. (SAMHSA, 2004) (4) Be familiar with the FDA final policy statement on Methadone that explicitly discusses the topic, Can Methadone be used for pain control. No separate registration is required to prescribe methadone for treatment of pain. (DEA, 2006) (5) Read the new prescribing information for Methadone and the new patient information section. (Roxane, 2006) (6) Multiple potential drug-drug interactions can occur with the use of Methadone. A complete list of medications should be obtained prior to prescribing methadone to avoid adverse events, and the patient should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications. This medication is indicated as a second-line agent in the treatment of chronic pain. The patient has been prescribed methadone since 2013. The patient has persistent and worsening pain. The long-term use of opioid therapy is only indicated when measurable outcomes in pain control and function have been achieved. The provided documentation fails to show these measurable outcome improvements, therefore the request has not met criteria as per the California MTUS guidelines and is not medically necessary.

Methadone 5mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Methadone.

Decision rationale: The California chronic pain medical treatment guidelines section on methadone states: Methadone Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it. (Clinical Pharmacology, 2008)Steps for prescribing methadone:(1) Basic rules- Weigh the risks and benefits before prescribing methadone.- Avoid prescribing 40 mg Methadone tablets for chronic non-malignant pain. This product is only FDA-approved for detoxification and maintenance of narcotic addiction.- Closely monitor patients who receive methadone, especially during treatment initiation and dose adjustments.(2) Know the information that is vital to give the patient:- Don't be tempted to take more methadone than prescribed if you are not getting pain relief. This can lead to a dangerous build-up that can cause death.- All changes in methadone dose should be made by your treating practitioner.- Methadone can make your breath slow down, or actually stop.- Methadone can slow down your heartbeat and you might not be able to detect this.- If you feel like you are having an irregular heartbeat, dizziness, light-headedness or fainting, call your doctor or clinic immediately. (FDA, 2006)(3) Be familiar with the current SAMHSA health advisory on methadone - The medication has become more accessible to unauthorized users.- It can accumulate in potentially harmful doses (especially during the first few days of treatment.- There has been a rise in Methadone-associated mortality. (SAMHSA, 2004)(4) Be familiar with the FDA final policy statement on Methadone that explicitly discusses the topic, "Can Methadone be used for pain control" No separate registration is required to prescribe methadone for treatment of pain. (DEA, 2006)(5) Read the new prescribing information for Methadone and the new patient information section. (Roxane, 2006)(6) Multiple potential drug-drug interactions can occur with the use of Methadone. A complete list of medications should be obtained prior to prescribing methadone to avoid adverse events, and the patient should be warned to inform any other treating physician that they are taking this medication prior to starting and/or discontinuing medications. This medication is indicated as a second-line agent in the treatment of chronic pain. The patient has been prescribed methadone since 2013. The patient has persistent and worsening pain. The long-term use of opioid therapy is only indicated when measurable outcomes in pain control and function have been achieved. The provided documentation fails to show these measurable outcome improvements, therefore the request has not met criteria as per the California MTUS guidelines and is not medically necessary.

Voltaren 10% Topical Gel 100gm 2 tubes, with 5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety, primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.

Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lends themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) Topical analgesic NSAID formulations are not indicated for long-term use and have little evidence for treatment of the spine, hip or shoulder. This patient does not have a diagnosis of osteoarthritis or neuropathic pain that has failed first line treatment options but rather the diagnosis of neck and shoulder pain. Therefore criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.

