

<b>Case Number:</b>	CM15-0130185		
<b>Date Assigned:</b>	07/15/2015	<b>Date of Injury:</b>	06/02/2007
<b>Decision Date:</b>	08/11/2015	<b>UR Denial Date:</b>	06/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/02/2015

### 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 57 year old female who sustained an industrial injury on 6-2-07. Diagnoses are lumbosacral spondylosis without myelopathy, other depression due to general medical condition, and sacroilitis. In a progress report dated 5-11-15, a treating physician notes pain in the mid and lower back. Pain is constant, sharp and shooting and rated at 7 out of 10. Medications that have been discontinued are Prilosec, Zoloft, and Elavil. Tenderness is noted in the right and left paravertebral regions at the L4-L5 and L5-S1 levels. Range of motion of the lumbar spine is restricted and painful. The injured worker continues to have intractable pain that continues to require medication. She has signed an opioid agreement. With medication she is able to perform activities of daily living. She reports approximately 30% improvement in function with the use of medications. Work status is noted that she is currently working. The requested treatment is Methadone 5 mg, 1 tablet twice a day as needed for 30 day #60, Norco 10-325 mg 1 tablet 3 times a day as needed for 30 days #90, Terocin apply to painful area 2-3 times per day, 1 patch as directed, for 30 days, #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Methadone 5mg tab, 1 tad BID as needed for 30 days #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Methadone, On-Going Management Page(s): 61-62, 78-80. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Methadone.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines methadone Page(s): 61-62.

**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 long-term use of opioid therapy is only indicated when measurable outcomes in pain control and function have been achieved. The included clinical documentation for review does not show failure of all first line pain agents. 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.

**Norco 10/325mg 1 tab 3 times a day as needed for 30 days #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines On-Going Management Page(s): 81, 79-80.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-84.

**Decision rationale:** The California chronic pain medical treatment guidelines section on opioids states for ongoing management: On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to non-opioid means of pain control.(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids (a) If the patient has returned to work. (b) If the patient has improved functioning and pain. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox- AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. There is no documented significant decrease in objective pain measures such as VAS scores for significant periods of time. There are no objective measures of improvement of function. Therefore all criteria for the ongoing use of opioids have not been met and the request is not medically necessary.

**Terocin New Apply to pain area 2-3 times per day, 1 patch as directed, as needed for 30 days #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111. Decision based on Non-MTUS Citation <http://www.drugs.com/otc/terocin.html>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**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 anti-depressants 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. The requested medication contains ingredients, which are not indicated per the California MTUS for topical analgesic use. Therefore the request is not medically necessary.