

<b>Case Number:</b>	CM15-0081517		
<b>Date Assigned:</b>	05/04/2015	<b>Date of Injury:</b>	05/27/2003
<b>Decision Date:</b>	06/02/2015	<b>UR Denial Date:</b>	04/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/28/2015

### 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 53 year old female who sustained an industrial injury on 05/27/2003. The injured worker was diagnosed with Reflex Sympathetic Dystrophy Syndrome (RSD) of the upper extremity, cervical spondylosis without myelopathy, cervicogenic headaches, cervical degenerative disc disease, myofascial pain/spasm and right shoulder pain. Treatment documented includes diagnostic testing, surgery, physical therapy, cervical spinal cord stimulator (SCS) and medications. The injured worker is status post arthroscopy right shoulder with rotator cuff repair (2006), subacromial decompression, revision of rotator cuff repair and bicep tendinosis (2008) and right shoulder revision rotator cuff repair and screw removal (2009). According to the primary treating physician's progress report on March 17, 2015, the injured worker reports an increase in overall pain since her last visit in January 2015. The injured worker rates her average pain level at 8/10, her mood level at 7/10 and functional level at 8/10 since that visit. The injured worker was doing yard work with weed whacking and both her shoulders subsequently hurt. She reports the medications are maintaining the pain at a tolerable level and sleep is okay at 4 hours a night. Examination demonstrated pain in the right arm greater than left from the ulnar to the shoulder level with neck pain and increased cervical spasms bilaterally. The injured worker continues with decreased range of motion of the right shoulder and neck due to pain. The spinal cord stimulator (SCS) and lead implant site is described as a burning pain. Severe spondylosis with crepitus is noted and is present on active range of motion of the cervical spine. Current medications are listed as Cambia, Celebrex, Lorzone, Lyrica, Methadone, Percocet and TN3 cream. Treatment plan consists of re-confirming informed opioid contract, continuing prescribed

medications, physical therapy and home exercise program on a regular basis, follow-up for conservative versus surgical options, follow up with removal of lead of spinal cord stimulator (SCS), right C3 through C6 medial branch block and the current request for Methadone 10mg #90 with 1 postdated prescription refill after 4/15/2015, Percocet 10/325 mg #120 with 1 postdated prescription refill after 4/15/2015 and a retrospective urine drug screening (DOS: 3/17/2015).

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Methadone 10mg #90 with 1 post dated Rx refill after 4/15/2015: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-80.

**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.

**Percocet 10/325 mg #120 with 1 post dated Rx refill after 4/15/2015: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids on-going Page(s): 76-80.

**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 nonadherent) 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 nonopioid 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 criteria for the ongoing use of opioids have not been met and the request is not medically necessary.

**Retrospective (UDS) Urine Drug Screen: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Urine Drug Screening Page(s): 43.

**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: 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 nonopioid 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. The California MTUS does recommend urine drug screens as part of the criteria for ongoing use of opioids .The patient was on opioids at the time of request and therefore the request is medically necessary.