

<b>Case Number:</b>	CM14-0170239		
<b>Date Assigned:</b>	10/20/2014	<b>Date of Injury:</b>	01/12/2002
<b>Decision Date:</b>	11/25/2014	<b>UR Denial Date:</b>	10/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/15/2014

### 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 North Carolina. 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:

The patient is 52-year-old with a reported date of injury of 01/12/2002. The patient has the diagnoses of chronic low back pain, lumbosacral degenerative disc disease, chronic pain syndrome, opioid dependence and depression/anxiety. Per the most recent progress notes provided for review by the primary treating physician dated 09/17/2014, the patient had complaints of back pain that radiates to the right lower extremity. The physical exam noted decreased range of motion in the lumbosacral spine with mild tenderness to palpation in the lumbosacral paraspinal muscles. Treatment plan recommendations included starts on methadone and continuation of Restoril and Endocet.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **30 Tablets of Methadone 5mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids criteria for use; Page(s): 61-62.

**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. In the progress notes the patient reports pain level as 3-5/10 without the use of this medication. The patient does have the diagnoses of chronic opioid dependence. There is however no provided documentation on why the patient would be switching to methadone and actual failure of first line treatment options. Therefore the request has not met criteria as per the California MTUS guidelines and is not certified.

### **60 Tablets of Methadone 10mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids criteria for use; Page(s): 61-62.

**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:MethadoneRecommended 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. In the progress notes the patient reports pain level as 3-5/10 without the use of this medication. The patient does have the diagnoses of chronic opioid dependence. There is however no provided documentation on why the patient would be switching to methadone and actual failure of first line treatment options. Therefore the request has not met criteria as per the California MTUS guidelines and is not certified.

#### **45 Tablets of Restoril 15mg with 5 Refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines; regarding Benzodiazepines

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines benzodiazepines Page(s): 24.

**Decision rationale:** The California chronic pain medical treatment guidelines section on benzodiazepines states: Benzodiazepines Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) The requested medication is not recommended for long term

use over 4 weeks duration. The medication is being used as a treatment for sleep disturbance. There is no documentation of failure of first line agent recommended for long term treatment of sleep disorders. Therefore the request is not certified due to the reasons as outline above.

## **270 Tablets of Endocet 10/325mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids criteria for use; short acting.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-86.

**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. 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)- 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. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007) The long-term use of this medication is not recommended unless certain objective outcome measures have been met as defined above. There is no provided objective outcome measure that shows significant improvement in function while on the medication or a return to work. There is no evidence of failure of other conservative treatment modalities for chronic pain. There is no documentation of significant improvement in VAS scores on the medication. For these reasons criteria for ongoing and continued use of the medication have not been met. Therefore the request is not certified.