

<b>Case Number:</b>	CM15-0141500		
<b>Date Assigned:</b>	07/31/2015	<b>Date of Injury:</b>	02/02/2001
<b>Decision Date:</b>	09/04/2015	<b>UR Denial Date:</b>	06/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/21/2015

### 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: Texas, California  
 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 57 year old male, who sustained an industrial injury on February 2, 2001, incurring low and mid and upper back injuries after lifting heavy mattresses. He was noted to have significant neurological changes. He was diagnosed with cervical disc disease, cervical radiculopathy, and cervicgia, bilateral. Treatment included steroids, anti-inflammatory drugs, pain management, neuropathic medications, epidural steroid injection, nerve blocks, transcutaneous electrical stimulation, antidepressants, heat and cold therapy and activity modifications. Currently, the injured worker complained of tenderness, stiffness and pain of the cervical, thoracic and lumbar spine with reduced range of motion. He complained of constant neck pain and increased discomfort with neck turning and use of his upper extremities. He noted difficulty staying awake during the day and always felt fatigued. The treatment plan that was requested for authorization included a prescription for Opana IR, one sleep study with consultation and laboratory testing. Per the note dated 7/29/15 the patient had complaints of pain in neck and back with radiculopathy at 9/10. The patient has had history of fall three times a week. Physical examination revealed antalgic gait normal psychological, cardiac and respiratory examination, alert and oriented and no acute distress. The patient had used single point cane for ambulation. The patient has had history of cervical spine stenosis. The patient has had notable improvement with Opana 7.5 twice a day in his painful symptoms. The patient has had UDS on 4/3/15 that was consistent. The patient has had history of depression. The medication list include Opana, antidepressants, Celebrex, Ultram, Gabitril, Effexor and Lyrica. The patient has had MRI brain in 2001 that revealed mild brain atrophy. The patient has had lab report on 6/12/15 that

revealed HBA1C 5.9, Testosterone 235, BUN 16, S. Creatinine 1.01, Glucose 103, Vit D 11, The patient had used a TENS unit for this injury. The patient has had history of HTN. The patient has had MRI of the cervical spine on 1/7/2015 that revealed disc central canal stenosis and degenerative changes. Patient had received ESIs for this injury. Past medicine list include Nexium, Percocet, Gabapentin, Morphine, Motrin, Ativan, Advair, Ultram, Valium, Ibuprofen and Prednisolone.

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

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

#### **Opana IR 10mg #90: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use: page 76-80 CRITERIA FOR USE OF OPIOIDS Therapeutic Trial of Opioids.

**Decision rationale:** Request Opana IR 10mg #90. Opana (oxymorphone) is an opioid pain medication used to treat moderate to severe pain. According to CA MTUS guidelines cited below, a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. The records provided do not specify that patient has set goals regarding the use of opioid analgesic. A treatment failure with non-opioid analgesics is not specified in the records provided. Other criteria for ongoing management of opioids are: The lowest possible dose should be prescribed to improve pain and function, continuing review of the overall situation with regard to non-opioid means of pain control. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. The records provided do not provide a documentation of response in regards to pain control and functional improvement to opioid analgesic for this patient. The continued review of overall situation with regard to non-opioid means of pain control is not documented in the records provided. As recommended by MTUS a documentation of pain relief, functional status, appropriate medication use, and side effects should be maintained for ongoing management of opioid analgesic, these are not specified in the records provided. He noted difficulty staying awake during the day and always felt fatigued. The patient has had history of a fall three times a week. Whether the sedation from opioids was contributing to these symptoms is not specified in the records provided. Whether improvement in pain translated into objective functional improvement including ability to work is not specified in the records provided. With this, it is deemed that, this patient does not meet criteria for ongoing continued use of opioids analgesic. The medical necessity of Opana IR 10mg #90 is not established for this patient, given the records submitted and the guidelines referenced, therefore is not medically necessary. If this medication is discontinued, the medication should be tapered, according to the discretion of the treating provider, to prevent withdrawal symptoms.

**One sleep study with consultation: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 07/15/15) Polysomnography.

**Decision rationale:** One sleep study with consultation; CA MTUS/ACOEM does not address this request, therefore ODG guidelines used. Per ODG cited below polysomnography/sleep study is, recommended after at least six months of an insomnia complaint (at least four nights a week), unresponsive to behavior intervention and sedative/sleep-promoting medications, and after psychiatric etiology has been excluded. Criteria for Polysomnography: In-lab polysomnograms/sleep studies are recommended for the combination of indications listed below: (1) Excessive daytime somnolence; (2) Cataplexy (muscular weakness usually brought on by excitement or emotion, virtually unique to narcolepsy); (3) Morning headache (other causes have been ruled out); (4) Intellectual deterioration (sudden, without suspicion of organic dementia); (5) Personality change (not secondary to medication, cerebral mass or known psychiatric problems); & (6) Insomnia complaint for at least six months (at least four nights of the week), unresponsive to behavior intervention and sedative/sleep-promoting medications and psychiatric etiology has been excluded. A sleep study for the sole complaint of snoring, without one of the above mentioned symptoms, is not recommended. The records provided did not specify if the above criteria for polysomnogram were present. A detailed clinical history regarding insomnia was not specified in the records provided. Per records provided, psychologically the patient had depression. It is unclear if untreated psychiatric etiology, as the cause of the insomnia, has been excluded. Response to sedative/sleep promoting medications (at night) and behavior intervention were not specified in the records provided. The effect of slowly decreasing and if necessary, discontinuing day time use of sedating medicines like opana, on the symptoms of day time sleepiness, is not specified in the records provided. The medical necessity of the request for One sleep study with consultation is not fully established for this patient, therefore is not medically necessary.

**One labs to include CMP, hemoglobin A1C, testosterone total, and vitamin D:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Routine Suggested Monitoring: page 70, Page 110 Testosterone replacement for hypogonadism (related to opioids).

**Decision rationale:** On labs to include CMP, hemoglobin A1C, testosterone total, and vitamin DA CMP (or BMP) can be ordered as part of a routine physical examination, or may be used to monitor a patient with a chronic disease, such as diabetes mellitus or hypertension. Per the cited guidelines, Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has

been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. As per the cited guideline Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or signs of hypogonadism. He noted difficulty staying awake during the day and always felt fatigued. The patient has had history of fall three times a week. The medication list include Opana, antidepressants, Celebrex, Ultram, Gabitril, Effexor and Lyrica. The patient has had history of HTN. Past medicine list include Nexium, Percocet, Gabapentin, Morphine, Motrin, Ativan, Advair, Ultram, Valium, Ibuprofen and Prednisolone. Patient is taking NSAIDs and opioids and had history of fatigue, weakness and falls. The pts medication list includes prednisolone which can alter glucose metabolism. A test for Hemoglobin A1C is also deemed medically appropriate and necessary. In addition, pt had symptoms of fatigue and a history of taking steroids. Vitamin D deficiency can contribute to fatigue and taking prednisone for long could cause osteoporosis. In this situation, a vitamin D level is also deemed medically appropriate and necessary. The request for the labs CMP, hemoglobin A1C, testosterone total, and vitamin D was deemed is medically appropriate and necessary.