

<b>Case Number:</b>	CM15-0166633		
<b>Date Assigned:</b>	09/14/2015	<b>Date of Injury:</b>	02/08/2000
<b>Decision Date:</b>	10/16/2015	<b>UR Denial Date:</b>	07/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/25/2015

### 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: Tennessee, Florida, Ohio  
 Certification(s)/Specialty: Surgery, Surgical Critical Care

### 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 8, 2000, resulting in pain or injury to the left wrist. A review of the medical records indicates that the injured worker is undergoing treatment for major depression, severe, psychological factors affecting medical condition, and pain disorder secondary to back injury. The psychiatric Interim report dated June 8, 2015, noted the injured worker took Bupropion, Lexapro, Saphris, Seroquel, and Clonazepam. The injured worker was also noted to take Opana ER, Percocet, Metaxalone, Flector patches, and Arthrotec for his orthopedic pain. The chronic pain was noted to have caused a chronically elevated cortizole level, thus he was on Foresta gel and Levitra. The injured worker was noted to take Vitamin D3 and Vitamin B12 for hypo-vitaminosis. The Treating Physician's report dated June 25, 2015, noted the injured worker with paroxysmal and persistent atrial fibrillation, having undergone two previous cardioversions, tolerating his current medications without side effects. The injured worker's current medications were listed as Amiodarone, Metoprolol, and Xarelto. The Physician's impression was recurrent atrial fibrillation, maintaining SR following cardioversion, paroxysmal supraventricular tachycardia, possibly intermittently symptomatic, resolved severe esophagitis, hypertension currently with borderline control, sleep apnea, and hyperlipidemia. The Physician noted the Xarelto was to be discontinued with the injured worker starting Aspirin 81mg every day. On March 26, 2015, the injured worker was noted to be somewhat nauseated, presumably from the Amiodarone therapy, with the dose decreased. On February 18, 2015, the injured worker's Digoxin was noted to be discontinued, starting Amiodarone. The treating physician indicates that a stress echo dated

February 18, 2015, was negative for ischemia. Prior treatments have included cortisone injections, direct current cardioversion on March 19, 2015, and medications. The Provider's request for authorization requested Testosterone Gel 10mg/act, TID, Amidoarone 200mg, BID, Bupropion HCL 300mg XL, every day, ASA 81mg, every day, Levitra Tab 20mg, every day, Digitek 0.25mg, every day, unspecified quantity, Clonazepam 1mg, QID, unspecified quantity, Diclo/Misopr Tab 75-0.2mg, BID, unspecified quantity, Metaxalone Tab 800mg, QID for 15 days, unspecified quantity, Flector Dis 1.3%, BID, unspecified quantity, Ondansetron Tab 8mg, TID, unspecified quantity, Saphris Sub 10mg, BID, unspecified quantity, Quetiapine 100mg, BID, unspecified quantity, Oxyco-APAP 10-325mg, 6 per day, unspecified quantity, and Opana 40mg ER, TID, unspecified quantity. The Utilization Review (UR) dated July 29, 2015, certified the requests for Levitra Tab 20mg, every day, ASA 81mg, every day, Testosterone Gel 10mg/act, TID, Bupropion HCL 300mg XL, every day, Amidoarone 200mg, BID, and non-certified the request for Digitek 0.25mg, every day, unspecified quantity, Clonazepam 1mg, QID, unspecified quantity, Diclo/Misopr Tab 75-0.2mg, BID, unspecified quantity, Metaxalone Tab 800mg, QID for 15 days, unspecified quantity, Flector Dis 1.3%, BID, unspecified quantity, Ondansetron Tab 8mg, TID, unspecified quantity, Saphris Sub 10mg, BID, unspecified quantity, Quetiapine 100mg, BID, unspecified quantity, Oxyco-APAP 10-325mg, 6 per day, unspecified quantity, and Opana 40mg ER, TID, unspecified quantity.

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

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

**Opana 40mg ER, TID, unspecified quantity: 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): Opioids for chronic pain, Opioids, criteria for use, Opioids, dosing.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The clinical records submitted do not support the fact that this patient has a dose, which does not exceed 120 mg oral morphine equivalents per day. In accordance with California MTUS guidelines, narcotics for chronic pain management should be continued if "(a) If the patient has returned to work, (b) If the patient has improved functioning and pain." MTUS guidelines also recommends that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. The dose of opioids prescribed this patient far exceeds that of 120mg oral morphine equivalents per day. Therefore, based on the submitted medical documentation, the request for Opana 40mg ER TID is not-medically necessary

**Oxyco/APAP 10/325mg, 6/day, unspecified quantity: 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): Opioids for chronic pain, Opioids, criteria for use, Opioids, dosing.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The clinical records submitted do not support the fact that this patient has a dose, which does not exceed 120 mg oral morphine equivalents per day. In accordance with California MTUS guidelines, narcotics for chronic pain management should be continued if (a) If the patient has returned to work, (b) If the patient has improved functioning and pain. MTUS guidelines also recommends that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. The dose of opioids prescribed this patient far exceeds that of 120mg oral morphine equivalents per day. Therefore, based on the submitted medical documentation, the request for oxycodone/PAP 10/325mg is not-medically necessary.

**Quetiapine 100mg, BID, unspecified quantity:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Online Version, Mental Illness & Stress, Atypical Antipsychotics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Atypical Antipsychotics.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. According to the Official Disability Guidelines (ODG), atypical antipsychotics are "Not recommended as a first-line treatment. Adding an atypical antipsychotic to an antidepressant provides limited improvement in depressive symptoms in adults, new research suggests. The meta-analysis also shows that the benefits of antipsychotics in terms of quality of life and improved functioning are small to nonexistent, and there is abundant evidence of potential treatment-related harm." Although the patient's severe depression and chronic pain are acknowledged, this patient's medical records do not demonstrate that they have tried and failed other first line therapies for depression. The most recent medical records do not demonstrate a quantifiable, objective improvement in the patient's depression secondary to use of this medication. Therefore, based on the submitted medical documentation, the request for seroquel is not medically necessary.

**Saphris Sub 10mg, BID, unspecified quantity:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Online Version, Mental Illness & Stress, Atypical Antipsychotics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Atypical Antipsychotics.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. According to the Official Disability Guidelines (ODG), atypical antipsychotics are "Not recommended as a first-line treatment. Adding an atypical antipsychotic to an antidepressant provides limited improvement in depressive symptoms in adults, new research suggests. The meta-analysis also shows that the benefits of antipsychotics in terms of quality of life and improved functioning are small to nonexistent, and there is abundant evidence of potential treatment-related harm." Although the patient's severe depression and chronic pain are acknowledged, this patient's medical records do not demonstrate that they have tried and failed other first line therapies for depression. Therefore, based on the submitted medical documentation, the request for saphris is not medically necessary.

**Ondansetron Tab 8mg, TID, unspecified quantity:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Ondansetron (Zofran), Antiemetics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Zofran FDA Prescribing Guidelines <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm271924.htm>.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address this topic. According to its FDA prescribing recommendations, "Ondansetron is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery." It is in a class of medications called 5-HT3 receptor antagonists and works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting. This patient has back pain which is currently being treated with opioids. The patient has not undergone surgery or been diagnosed with the need for chemotherapy/radiation. Thus, the requested medication is being prescribed against FDA indications. Therefore, based on the submitted medical documentation, the request for Ondansetron is not medically necessary.

**Flector Dis 1.3%, BID, unspecified quantity:** 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): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, specific drug list & adverse effects.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. Per the California MTUS guidelines, topical NSAIDs are only recommended for "Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment." They should only be use for 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. Use for neuropathic pain is not recommended as there is no evidence to support use. This patient has been documented to have long term, chronic neuropathic and musculoskeletal pain to the thoracic and lumbar spine. Per MTUS, topical NSAID application is not warranted for this indication. Therefore, based on the submitted medical documentation, the request for flector 1.3% is not medically necessary.

**Metaxalone Tab 800mg, QID for 15 days, unspecified quantity:** 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): Muscle relaxants (for pain).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. In accordance with the California MTUS guidelines, Cyclobenzaprine is a muscle relaxant and muscle relaxants are not recommended for the treatment of chronic pain. From the MTUS guidelines: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic back pain. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence." This patient has been diagnosed with chronic back pain of the lumbar and thoracic spine. Per MTUS, the use of a muscle relaxant is not indicated. Therefore, based on the submitted medical documentation, the request for metaxalone is not medically necessary.

**Diclo/Misopr Tab 75-0.2mg, BID, unspecified quantity:** 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): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The California MTUS guidelines address the topic of NSAID prescriptions by stating, a Cochrane review of the literature on drug relief for low

back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. The MTUS guidelines do not recommend routine use of NSAIDs due to the potential for adverse side effects (GI bleeding, ulcers, renal failure, etc). This patient already has gastric complaints of chronic nausea and upset stomach; which is a contraindication to NSAID use. The medical records do not support that the patient has a contraindication to other non-opioid analgesics. Therefore, medical necessity for diclofenac/misoprostol prescription has not been established.

**Clonazepam 1mg, QID, unspecified quantity:** 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): Benzodiazepines.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. Per the California MTUS guidelines, benzodiazepines are: "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." This patient has been documented to have long term, chronic neuropathic and musculoskeletal pain to the thoracic and lumbar spine. Per MTUS, benzodiazepines should not be utilized for treatment of chronic pain. The patient has been prescribed clonazepam for longer than 4 weeks and is at high risk for dependence. Therefore, based on the submitted medical documentation, the request for clonazepam is not medically necessary.

**Digitek 0.25mg, everyday, unspecified quantity:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/mtm/digitek.html>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Prescribing Guidelines and Indications for Digoxin [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/020405s0041bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020405s0041bl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address this topic. Digoxin is a cardiac medication, which inhibits sodium-potassium ATPase. Inhibition of the enzyme leads to an increase in the intracellular concentration of sodium and an increase in the intracellular concentration of calcium. The beneficial effects of digoxin result from direct actions on cardiac muscle, as well as indirect actions on the cardiovascular system mediated by effects on the autonomic nervous system. The FDA prescribing guidelines state that digoxin is indicated for the treatment of mild to moderate heart failure. A review of the medical documentation does support

that this patient has had a history of refractory atrial fibrillation with cardioversion. However, recent medical records state that digoxin has been discontinued in favor of amiodarone therapy. There is no indication that digoxin has been re-prescribed for rate control of this patient's atrial fibrillation. Therefore, based on the submitted medical documentation, the request for digoxin is not-medically necessary.