

<b>Case Number:</b>	CM14-0122998		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	02/19/2014
<b>Decision Date:</b>	10/27/2014	<b>UR Denial Date:</b>	07/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/04/2014

### 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 Occupational Medicine and is licensed to practice in California. 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 injured worker is a 63-year-old quality control assistant reported low back pain after twisting to avoid a falling dumpster lid as he was throwing away papers on 2/19/14. He has not worked since 2/20/14. The primary treating physician, an orthopedist, first evaluated the patient on 3/26/14. Documented past medical history included diabetes and hypertension, and documented medications included insulin, metformin and lisinopril. There were no documented GI problems or complaints. Exam was notable for marked obesity, mild low back tenderness and decreased range of motion, with no findings of radiculopathy. Diagnosis was lumbosacral strain, and treatment plan was 12 PT sessions. No mention was made of the patient's current medications for his injury or of any plan to continue or change them. Per a 3/19/14 physical therapy note (from one week before), the patient was taking Naproxen, Robaxin, Vicodin, Metformin, and Benazepril. A 4/18/14 progress note signed by a physician's assistant documents ongoing low back pain and similar physical findings. 12 visits of physical therapy were re-requested. Voltaren 75 mg #60 with 2 refills, Ultram 50 mg #60 with 2 refills and Ambien 10 mg qhs for insomnia related to pain #30 with 2 refills were prescribed. The requests for these treatments were modified in UR to 6 physical therapy sessions and #60 only of all three medications, without refills. There are no further progress noted from the primary treating physician in the available records. A UR report dated 7/29/14 makes reference to a progress note dated 7/3/14. Per the UR report, on that date the patient was complaining of neck and low back pain. He still had low back tenderness and limited range motion. (These findings appear unchanged or perhaps worse from the previous visits, since they did not include mention of neck pain.) There is no mention of any improvement in function. Requests for Ultram 50 mg #60 with 2 refills, Ambien 10 mg, #30 with 2 refills, and Voltaren 75 mg, quantity # 60 with 2 refills were all non-certified. A request for IMR regarding these decisions was made.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective request for Ultram 50 MG # 60 with 2 refills DOS 7/3/14:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Criteria for Use of Opioids, Steps to Take Before a Therapeutic Tr.

**Decision rationale:** Per the MTUS recommendations cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. If opioids are used, it is recommended that goals for pain and function be set and monitored. Opioids should be discontinued if there is no improvement in function. There is no good evidence that opioids are effective for radicular pain. If long-term use of opioids occurs, there is a need for ongoing pain and function assessments, as well as assessments for side effects, of other concurrent treatments, and of concurrent psychological issues. Ultram is brand-name Tramadol, which is a centrally acting opioid analgesic. The clinical findings in this case do not support its use. It was started in conjunction with 2 other medications, making it impossible to determine if resultant positive or negative effects are in fact due to tramadol. There is no evidence that the patient's function was carefully assessed or that any functional goals for treatment were set. There appears to have been no improvement in either pain or range of motion after the patient had been on tramadol for nearly 4 months. It can be presumed that the patient's functional level has not significantly improved since his work status is unchanged. There is no documentation of ongoing assessment for function, for side effects or for concurrent psychological issues. Therefore, the request for Ultram 50 mg #60 with two refills is not medically necessary.

**Retrospective request for Ambien 10 MG # 30 with 2 refills DOS:7/3/14:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NIH, MedlinePlus, Zolpidem

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain Page(s): 60. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), insomnia chapter

**Decision rationale:** Per the MTUS Guidelines, medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. Per the Official Disability Guidelines (ODG) reference above, treatment of insomnia should be based on its etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a

psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific components of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Zolpidem [Ambien] is indicated for the short-term (7-10 days) treatment of insomnia with difficulty of sleep onset. It is a schedule IV controlled substance, which means it has potential for abuse and dependency. Side effects include headache, daytime drowsiness, dizziness, blurred vision, confusion, abnormal thinking and bizarre behavior. Sleep driving and other activities for which the patient has no recollection may occur. The medication should be discontinued if the latter occurs. Abrupt discontinuation may lead to withdrawal. Dosing: Ambien 5 to 10 mg at bedtime (5 mg in women, the elderly and patients with hepatic dysfunction). Adults who use zolpidem have a greater than 3-fold increased risk for early death, according to results of a large matched cohort survival analysis. The clinical findings in this case do not support the use of Ambien. It was started in conjunction with two other medications, making it impossible to determine if resultant positive or negative effects are in fact due to Ambien. There was no documented evaluation of the etiology or type of the patient's insomnia, so it is unclear if it is the appropriate medication for the patient's sleep difficulties. The only documented statement by a provider regarding etiology is that it was prescribed for insomnia related to pain. This would mean that the patient has secondary insomnia, for which a sedative hypnotic is not necessarily indicated. The form of Ambien prescribed is short acting, which is not indicated for more than 10 days. There is no documentation of improvement in function or of sleep as a result of taking Ambien. Based on the evidence-based references cited and the clinical findings in this case, Ambien is not medically indicated. Furthermore, there is no assessment of the patient's insomnia documented, and there is no documentation of any improvement in function or sleep which might outweigh its potential side effects; as well the use of Ambien is not indicated for over 10 days. Therefore, the request for Ambien 10 mg #30 with 2 refills is not medically necessary and appropriate.

**Retrospective request for Voltaren 75 MG # 60 with 2 refills DOS:7/3/14: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, NSAIDs (non-steroidal anti-inflammatory drugs), Chronic low back p.

**Decision rationale:** MTUS guidelines cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The MTUS references regarding NSAIDs state that NSAIDs are recommended as an option for short-term symptomatic relief of chronic low back pain. A Cochrane review found that NSAIDs were no more effective than acetaminophen, narcotics or muscle relaxants; and that they were likely to have more side effects than acetaminophen and less side effects than narcotics or muscle relaxants. NSAIDs may be used to treat breakthrough and mixed pain conditions such as osteoarthritis with neuropathic pain, but there is there is only inconsistent evidence to support their use for long-term neuropathic pain. Clinicians should weight the indications for NSAIDs

against both GI and cardiovascular risk factors. They should determine if the patient is at risk for GI events. Risk factors include age over 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of aspirin, corticosteroids, or an anticoagulant; or high-dose or multiple NSAIDs, or an NSAID combined with aspirin. Patients with no GI risk factors and no cardiovascular disease may be prescribed a non-selective NSAID. Those at intermediate risk for GI disease should receive a non-selective NSAID plus a proton pump inhibitor (PPI) or misoprostol; or a Cox-2 selective NSAID. Patients at high GI risk should receive a Cox-2 selective NSAID and a PPI if an NSAID is absolutely necessary. This reference notes that long-term PPI use has been shown to increase the risk of hip fracture. A non-pharmacological choice should be the first option in patients with cardiovascular risk factors. In patients with mild to moderate risk factors, full-dose naproxen is the treatment of choice for long term or high dose therapy. NSAIDs are relatively contraindicated in patients with renal insufficiency or cirrhosis. Voltaren is brand-name diclofenac, which is a non-selective NSAID. The clinical findings in this case do not support the use of Voltaren. It was started in conjunction with two other medications, making it impossible to determine if either resultant positive or negative effects are in fact due to Voltaren. There is no evidence that the patient's function was carefully assessed or that any functional goals for treatment were set. There appears to have been no improvement in either pain or range of motion after the patient had been on Voltaren for nearly 4 months. It can be presumed that the patient's functional level has not significantly improved since his work status is unchanged. There is no documentation of any flare of the patient's chronic low back pain which would require NSAID use. There is no documentation of the patient's cardiovascular or GI risk factors, or of his level of renal function. The patient has diabetes, which is an equivalent for coronary artery disease. He also has hypertension. Both conditions put him at risk for cardiovascular disease and for renal disease. Based on the evidence-based citations above and the clinical findings in this case, the request for Voltaren 75 mg #60 with 2 refills is not medically necessary and appropriate.