

<b>Case Number:</b>	CM15-0026264		
<b>Date Assigned:</b>	02/18/2015	<b>Date of Injury:</b>	09/11/2007
<b>Decision Date:</b>	04/02/2015	<b>UR Denial Date:</b>	02/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/11/2015

### 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: Massachusetts

Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 71 year old female, who sustained an industrial injury on 9/11/2007. She has reported right sided pain after a fall including right shoulder, right hand, right knee and right foot pain. The diagnoses have included acute severe sprain with early onset reflex sympathetic dystrophy right ankle/foot, contusion of right hip and right knee. Treatment to date has included Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), psychological evaluation, and steroid injection. Currently, the IW complains of right ankle pain and swelling. On 11/18/14, physical examination documented sensory defect to bilateral upper extremities, balancing difficulty, ambulation with a cane and limp. Magnetic Resonance Imaging (MRI) of the right ankle from 7/24/14 revealed no acute findings. The plan of care included psychiatric follow up care, continued use of the cane for ambulation and continued previously prescribed medications. On 2/10/2015 Utilization Review non-certified Ambien 10mg #30 with two refills and Ibuprofen 600mg one tablet twice a day #60 with two refills, noting the documentation did not support medical necessity. The MTUS Guidelines were cited. On 2/11/2015, the injured worker submitted an application for IMR for review of Ambien 10mg #30 with two refills and Ibuprofen 600mg one tablet twice a day #60 with two refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ambien 10mg QTY:30 refill:2:** 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) Pain Chapter; Mental and Stress Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain (Chronic) Ambien (Zolpidem).

**Decision rationale:** Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008) See Insomnia treatment. Ambien CR offers no significant clinical advantage over regular release zolpidem. Ambien CR is approved for chronic use, but chronic use of hypnotics in general is discouraged, as outlined in Insomnia treatment. Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. (Ambien & Ambien CR package insert) Cognitive behavioral therapy (CBT) should be an important part of an insomnia treatment plan. A study of injured workers with persistent insomnia found that the addition of zolpidem immediate release to CBT was modestly beneficial during acute (first 6 weeks) therapy, but better long-term outcomes were achieved when zolpidem IR was discontinued and maintenance CBT continued. (Morin, 2009) Due to adverse effects, FDA now requires lower doses for zolpidem. The dose of zolpidem for women should be lowered from 10 mg to 5 mg for IR products (Ambien, Edluar, Zolpimist, and generic) and from 12.5 mg to 6.25 mg for ER products (Ambien CR). The ER product is still more risky than IR. In laboratory studies, 15% of women and 3% of men who took a 10-milligram dose of Ambien had potentially dangerous concentrations of the drug in their blood eight hours later. Among those who took Ambien CR, the problem was more common: 33% of women and 25% of men had blood concentrations that would raise the risk of a motor vehicle accident eight hours later. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. (FDA, 2013) According to SAMHSA, zolpidem is linked to a sharp increase in ED visits, so it should be used safely for only a short period of time. According to the documents available for review, the injured worker does not carry diagnoses of insomnia. Furthermore the injured worker has been using this medication for long-term treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

**Ibuprofen 600mg QTY:60 refills: 2:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS  
Page(s): 67, 70-73.

**Decision rationale:** According to the MTUS Antiinflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) Recommended with cautions below.

**Disease-State Warnings for all NSAIDs:** All NSAIDS have[U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDS should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. Other disease-related concerns(non-boxed warnings):

**Hepatic:** Use with caution in injured workers with moderate hepatic impairment and not recommended for injured workers with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of injured workers taking NSAIDs. **Renal:** Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. **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. Routine blood pressure monitoring is recommended.

**Overall Dosing Recommendation:** It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual injured worker treatment goals. According to the documents available for review, it appears that the injured worker is taking this medication for long-term therapy of a chronic condition. Given the increased risks associated with long-term use of this medication and no documented evidence that the lowest possible dose is being used for the shortest period of time, the requirements for treatment have not been met and medical necessity has not been established.