

Case Number:	CM15-0086525		
Date Assigned:	05/08/2015	Date of Injury:	02/11/1990
Decision Date:	06/16/2015	UR Denial Date:	04/14/2015
Priority:	Standard	Application Received:	05/05/2015

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 64-year-old male who sustained an industrial injury on 2/11/1990. His diagnoses, and/or impressions, are noted to include right hip osteoarthritis; chronic pain syndrome secondary to post-lumbar laminectomy syndrome with radiculopathy; lower back pain; sciatica; thoracic radiculopathy; spinal enthesopathy; and fasciitis. No current imaging studies are noted. The history of his treatments have included multiple diagnostic studies; low back surgery in 1997; physical therapy; acupuncture; non-steroidal anti-inflammatories; transcutaneous electrical nerve stimulation unit therapy; epidural steroid injection therapy; and various 6 month medication trials which provided only short-lived benefits or no benefit at all, and were discontinued; and rest from work. More recent treatments are noted to include Cortisone injection therapy to the right hip (2/26/2015); low-impact home exercises; practicing good body mechanics; Lidocaine patches, effective on his neuropathic pain and increasing functionality; trans-dermal pain creams, helpful with muscle aches; rest from work; Mobic, Ambien, and Omeprazole. Progress notes of 2/5/2015 reported continuation of constant, severe low back pain with bilateral radiculopathy, left > right, that shoots through the buttock, into the right groin and down the leg, associated with tingling, and improved with medication. It was reported that he has tried a variety of pain killers over the past 10 years but all medications were discontinued to side effects, these included Gabapentin; that Lidocaine patch was helpful, without side effects, but was only approved for 1 month; transdermal pain creams provide some help with muscle aches; that he experiences anxiety, anger, sleep disturbances and nightmares from the pain; that he is apprehensive to try any medications; is not persuaded to try the

percutaneous electrical nerve stimulation (PENS) treatments or spinal cord stimulator trial. Also noted is that he had been approved for both the PENS and the spinal cord stimulator but was refusing at that time. Objective findings were noted to include tender and restricted lumbar - sacral spine range-of-motion due to pain; lumbosacral facet tenderness with positive lumbar facet loading maneuvers. The physician's requests for treatments were noted to include the continuation of Omeprazole, Ambien and Mobic.

IMR ISSUES, DECISIONS AND RATIONALES

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

30 Capsules of Omeprazole 20mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk, Proton-pump inhibitor.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines PPI Page(s): 68-69.

Decision rationale: The MTUS makes the following recommendations for the use of proton pump inhibitors. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the injured worker is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Recommendations Injured workers with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Injured workers at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Injured workers at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if necessary. Injured workers at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardio protection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. Cardiovascular disease: A non-pharmacological choice should be the first option in injured workers with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. According to the records available for review the injured worker does not meet any of the guidelines required for the use of this medication therefore, at this time, the requirements for treatment have not been met and medical necessity is not medically necessary.

30 Tablets of Ambien 10mg: 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, Zolpidem.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ambien.

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 is not necessary.

30 Tablets of Mobic 15mg: 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): 70-73.

Decision rationale: According to the MTUS Anti-inflammatories is 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 is not necessary.