

<b>Case Number:</b>	CM14-0142688		
<b>Date Assigned:</b>	09/10/2014	<b>Date of Injury:</b>	07/28/2004
<b>Decision Date:</b>	10/10/2014	<b>UR Denial Date:</b>	08/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/03/2014

### 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 Anesthesiology and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 57 year old female. The date of injury is July 28, 2004. The patient sustained an injury to the bilateral hands and fingers. The specific mechanism of injury was not elaborated on in the notes available for review. The patient currently complains of pain in pain in the bilateral hands and fingers worse with movement. The patient is maintained on the multimodal pain medication regimen including alprazolam, dexilant, ibuprofen and ambien. A request for Alprazolam, Dexilant, Ibuprofen and Ambien was denied.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Alprazolam tablets 1 mg, sixty count:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46 and 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** According to the MTUS, 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. Their range of action includes sedative/hypnotic, anxiolytic,

anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) Therefore, the request for Alprazolam tablets 1 mg, sixty count is not medically necessary and appropriate.

**Dexilant DR caplets 60 mg, thirty count:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

**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 patient 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 Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients 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 cardioprotection) 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 patients 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 patient 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. Therefore, the request for Dexilant DR caplets 60 mg, thirty count is not medically necessary and appropriate.

**zolpidem tablets 10 mg, thirty count:** 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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (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 patients 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 patient has been taking this medication for long term management of insomnia. This is in contrast to the Official Disability Guidelines (ODG) recommendations. Therefore, at this time, the requirements for treatment have not been met. The request for Zolpidem tablets 10 mg, thirty count is not medically necessary and appropriate.