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| Case Number: | CM14-0012569 | | |
| Date Assigned: | 02/21/2014 | Date of Injury: | 05/16/2011 |
| Decision Date: | 06/26/2014 | UR Denial Date: | 01/15/2014 |
| Priority: | Standard | Application Received: | 01/31/2014 |

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 Psychiatry 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:

36 years old male with date of injury 5/16/2011. Date of UR decision was 1/15/2014. Injury occurred when a heavy item fell on his left leg and it was partially bent over a railroad tie. It resulted in a severe proximal tibial fracture and an open reduction was performed. He developed pulmonary embolism after the surgery. Report from 05/06/2013 states that he uses ambien with good results to get him to sleep, but notes that he still awakens at night due to left leg pain. Per that report IW has reached maximum medical improvement and is now permanent and stationary. PR from 09/09/2013 states that his left knee pain is worse, continuous and having difficulty with ADL's. He is still tolerating modified work with daily pain. He continues to take norco with some relief. Psychiatric review of system is negative for depression, anxiety, memory loss, mental disturbance, suicidal ideation, hallucinations, paranoia. Per report from 10/25/2013 indicates a pain level of 9/10 in intensity without pain medications and 5/10 with Norco. PR from 12/11/2013 suggests that IW is requesting for refill on norco for left knee pain and also ambien due difficulty falling asleep due to the same.

IMR ISSUES, DECISIONS AND RATIONALES

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

AMBIEN 10 MG # 30 1 REFILL INSOMNIA: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) <Chronic Pain>, <Zolpidem >

Decision rationale: MTUS is silent regarding this issue. ODG states "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." The IW has been on Ambien for over a year. Medical necessity of continued use of Ambien cannot be affirmed at this time. It has risk of tolerance, dependence and safety hazards associated with continued long term use as described above. Therefore, the request for Ambien 10 mg # 30 1 refill insomnia is not medically necessary and appropriate.