MAXIMUS Federal Services

Case Number:	CM15-0085143		
Date Assigned:	05/08/2015	Date of Injury:	04/11/2006
Decision Date:	06/12/2015	UR Denial Date:	04/17/2015
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 52 year old male who sustained an industrial injury on 4/11/06. The mechanism of injury is unclear. He complains of right sided low back pain with no radiation, recurrent ear pain. Medications are ibuprofen, Lactulose, hydrocodone-acetaminophen 10-325 mg, ketoprofen, zolpidem, cortisporin, BenGay ultra strength, Penlac, omeprazole, famotodone, sertraline. Diagnoses include acute low back pain; external otitis media. There is a request for zolpidem to be taken at bedtime. The records available for review are unclear regarding the injured workers sleep issues.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zolpidem tartrate ER 12.5 mg #30 (Dispensed on 2/26/15): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA, Official Disability Guidelines (ODG), Ambien (Zolpidem), 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) Ambien.

Decision rationale: Zolpidem is a prescription short-acting non-benzodiazepine 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 has been using this medication for long-term treatment in contrast to the ODG indication above for short term use. Therefore, at this time, the requirements for treatment have not been met. Therefore the request is not medically necessary.