MAXIMUS Federal Services

Case Number:	CM14-0082609		
Date Assigned:	07/25/2014	Date of Injury:	02/07/1995
Decision Date:	09/18/2014	UR Denial Date:	05/06/2014
Priority:	Standard	Application Received:	06/03/2014

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 Internal medicine and is licensed to practice in Arizona. 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:

The claimant is a 49-year-old female who sustained an injury on February 7, 1995, while shifting and handling files. A request for Ambien CR 12.5 mg tablet quantity 100 was non-certified in May 2014. The reason for using this medication is because the patient has severe cervicogenic headaches, severe neck pain, left cervical radiculopathy and chronic pain causing insomnia. She has had 2 remote cervical surgeries with a resultant 4 level fusion from C3-C7. As far back as September 2000 the patient used Ambien to help her with her sleep. It is unclear if she has tried or used other remedies for sleep. On September 4, 2013, her pain specialist documented her current medications as Percocet 10/325 6 times a day, Diclofenac 75 mg twice a day, Soma 350 mg 4 times a day when necessary, Ambien CR 12.5 mg 1 daily at bedtime. Previously failed medication trials include: Vicodin ES, Norco, Ibuprofen, Nucynta, Dilaudid, Baclofen, Etodolac, Butrans patch, Gabapentin. It is possible that the patient has not tried some of the typical medications such as a tricyclic antidepressant i.e. Nortriptyline or Trazodone. Other possibilities would include Cymbalta, Doxepin, and Remeron. The physician who manages the patient's pain in September 2013 stated that the Ambien improves her quality of sleep as well as the duration of her sleep and again states that the insomnia is secondary to frequent awakening by pain. The patient had an additional evaluation with a different pain specialist at [redacted] who recommended that her current regimen remain unchanged. The patient has tried numerous things for her pain outside of medications and surgery which includes physical therapy, trigger points and epidurals (very helpful). She seemingly has not tried a cognitive behavioral therapy (CBT) program.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ambien CR 12.5mg, 100CN: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 22,29,46,80. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 12th edition (web), Pain (updated 11/06/2012).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG -TWC), ODG Treatment IntegratedTreatment/Disability Duration Guidelines, Chronic Pain. Zolpidem Other Medical Treatment Guideline or Medical Evidence: UpToDate, Treatment of Insomnia, Nonbenzodiazepines.

Decision rationale: Zolpidem is a prescription short-acting non-benzodiazepine hypnotic, which is approved for the short-term (usually 2-6 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. 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. 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. Due to adverse effects, FDA now requires lower doses of zolpidem. The lower dose of zolpidem for women should be lowered from 10-5 mg for IR products and from 12.5 mg to 6.25 mg for ER products. Ambien ER product is still more risky than IR. In laboratory studies, 15% of women and 3% of men who took a 10 mg dose of Ambien had potentially dangerous concentrations of the drug in the blood 8 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 8 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. Zolpidem is linked to a sharp increase in emergency department visits, so it should be used safely for only a short period of time. Clearly, as defined by the ODG above, Ambien CR 12.5mg is not good for long term management of insomnia, even if associated with chronic pain. This claimant has been taking the CR formulation at the higher dose (12.5 mg) which has been found to cause residual problems long after awakening in the morning. Taking Ambien has also been found to possibly worsen pain and depression long-term. It can impair function and memory more than opioid pain relievers. For all of these reasons ongoing usage of Ambien CR 12.5 mg is not recommended. Instead this patient might be considered for cognitive behavioral therapy. If pharmacotherapy is considered still necessary for helping with insomnia, perhaps consideration should be made for other options known to offer potential benefit to sleep, which

also have the potential for helping the chronic pain, such as Amitriptyline, Cymbalta, and Lyrica. For the reasons stated above, Ambien Cr 12.5 mg is deemed not medically necessary.