

<b>Case Number:</b>	CM15-0040802		
<b>Date Assigned:</b>	03/11/2015	<b>Date of Injury:</b>	10/03/2002
<b>Decision Date:</b>	08/04/2015	<b>UR Denial Date:</b>	02/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/03/2015

### 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: California  
Certification(s)/Specialty: Internal Medicine

### 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(n) 56 year old male, who sustained an industrial injury on 10/3/02. He reported pain in his lower back and bilateral knees after lifting a heavy object. The injured worker was diagnosed as having chronic low back pain with right sciatica, status post lumbar decompression and fusion and probable right L5 radiculopathy. Treatment to date has included OxyContin, Percocet, Norco, physical therapy, bilateral knee cortisone injections and a lumbar epidural injection. There is no documentation regarding the injured worker's sleep quality or sleep disturbances. As of the PR2 dated 5/28/13, the injured worker reports persistent right knee pain. He is status post right total knee arthroplasty on 1/28/13. The treating physician noted decreased range of motion and normal mood. This is the most recent progress note submitted for review. The treating physician requested Nuvigil 250mg #30 and Zolpidem 10mg #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nuvigil 250mg, #30:** 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), Armodafinil (Nuvigil).

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

**Decision rationale:** Based on ODG guidelines, Nuvigil is not recommended solely to counteract sedation effects of narcotics. Armodafinil is used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. It is very similar to Modafinil. Studies have not demonstrated any difference in efficacy and safety between armodafinil and modafinil. (Tembe, 2011) For more information, see also Modafinil (Provigil), where it is not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing, and it is noted that there should be heightened awareness for potential abuse of and dependence on this drug. Recently Cephalon produced a campaign advertising Nuvigil's ability to help shift workers stay alert on the job without impeding their ability to sleep during the day. The FDA is conducting an investigation into the possibility that this advertising or promotional information may have violated current regulations. (SEC, 2011) In this case, the patient does suffer from excessive sleepiness but it is not related to narcolepsy or shift work sleep disorder. It is likely secondary to his other medication side effects. Since Nuvigil is not used to counteract sedation effects of narcotics, the request for Nuvigil 250 mg #30 is not medically necessary.

**Zolpidem 10mg, #30:** 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), Zolpidem (Ambien).

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

**Decision rationale:** Based on ODG guidelines, Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is recommended for short-term (7-10 days) 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. See the Mental Chapter. Based on ODG guidelines, only short term zolpidem use is recommended due to the myriad of potential side effects and also it may be habit forming. Therefore, the request for Zolpidem 10 mg #30 (30 days worth) is not medically necessary.