

<b>Case Number:</b>	CM15-0189517		
<b>Date Assigned:</b>	10/01/2015	<b>Date of Injury:</b>	08/17/2007
<b>Decision Date:</b>	12/03/2015	<b>UR Denial Date:</b>	08/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/25/2015

### 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: Emergency 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 58-year-old male who sustained an industrial injury on 8-17-2007. Diagnoses have included herniated lumbar disc without myelopathy, shoulder pain, and constipation. Lumbar MRI dated 2-28-2015 revealed mild lumbar spondylosis and stable "post fusion changes at L4-5." Right shoulder x-ray 2-27-2015 found calcific tendonitis and mild osteoarthritis. Documented treatment includes a discectomy performed 2-20-2009 and fusion in 5-2010 stated to have "failed to help him." Documentation also references physical therapy "not helping," epidurals making "condition worse" and medication including Cymbalta, Hydrocodone-Acetaminophen, and Valium stated to be used for sleep on 4-26-2015. He stated he had "flushed Tramadol down the toilet because it was not helpful." He has been treated with OxyContin present in the medical records for at least six months stated by the physician 7-22-2015 as being "the only thing that seems to help," but a periodic report dated 4-16-2015 reports he is "Not on any pain meds except for valium hs." On 8-18-2015 the injured worker reported mid and low back pain with numbness and weakness in his lower extremities and weakness in both hands and forearms. On 4-29-2015 he reported "whole body pain, neuropathy pain, and insomnia." At the prior visit on 7-22-2015 he stated he has not been able to lie comfortably and bought an adjustable bed providing "some relief." Objective assessment noted he "walks in a very slow fashion, holding arms up from the elbows, appearing to be in a moderate amount of pain." There is no documentation regarding an opioid contract or recent urine drug screening, alternate forms of sleep hygiene being tried, or non-pharmacological attempts to treat constipation. The treating physician's plan of care includes requests for Movantik, Oxycontin and

Ambien CR; and, one adjustable bed. This request was denied on 8-26-2015. The injured worker is not presently working.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **Movantik 25mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Management of Opioids Therapy for Chronic Pain Working Group VA/DoD clinical practice guideline for management of opioids therapy for chronic pain. Washington (DC): Department of Veterans Affairs, Department of Defense; 2010 May. 159 p.

**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)/Opioid-induced constipation treatment.

**Decision rationale:** The request is for a medication to aid in constipation. The Official Disability Guidelines state the following regarding this topic: Recommended as indicated below. In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications don't work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for non-cancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic non-cancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza) shows efficacy and tolerability in

treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 mL for the treatment of opioid-induced constipation in patients taking opioids for non-cancer pain. (FDA, 2014) As stated above, measures to combat constipation for patients on opioids are needed. In this case, the use of this medication is not indicated. The patient is currently on a medication in the opioid class with the resultant side effect of constipation. The opioid medication has been non-certified for use. As such, there is lack of need for this medication. The request is not medically necessary.

**Oxycontin 10mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. As part of the pain treatment agreement, it is advised that "Refills are limited, and will only occur at appointments." In this case, there is inadequate documentation of persistent functional improvement seen. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Ambien CR 12.5mg #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).

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

**Decision rationale:** The request is for the use of zolpidem. The official disability guidelines state the following regarding the use of this medication: Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment for zolpidem (brand names Ambien, Edluar, Intermezzo, Zolpimist). See also the Pain Chapter. Zolpidem is approved for the short-term (usually two to six weeks) treatment of insomnia. 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, and Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. Due to adverse effects, FDA now requires lower doses for zolpidem. The ER product is still more risky than IR. 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. (Pain Chapter) Emergency department (ED) visits for adverse reactions related to zolpidem increased by almost 220% in a recent 5-year period, according to the Substance Abuse and Mental Health Services Administration (SAMHSA). Women and the elderly appear to be most prone to adverse reactions linked to zolpidem. Doctors should look at alternative strategies for treating insomnia such as sleep hygiene. By 2010 there were 64,175 ED visits involving zolpidem. The report stresses that zolpidem should be used safely for only a short period of time. (SAMHSA, 2013) Zolpidem (Ambien) increases the ability to remember images, but only those that have negative or highly arousing content. The findings have potential ramifications for patients prescribed zolpidem for relief of insomnia due to anxiety disorders, including posttraumatic stress disorder (PTSD). Physicians should watch out for this countertherapeutic effect in patients with anxiety disorders and PTSD, because these are people who already have heightened memory for negative and high-arousal memories. The study also identified sleep spindles as the mechanism that enables the brain to consolidate emotional memory. Sleep spindles are brief bursts of brain activity that occur primarily during non-rapid eye movement (REM) sleep. (Kaestner, 2013) New analysis from SAMHSA shows that overmedicating with zolpidem led to a near doubling of emergency department (ED) visits during the periods 2005-2006 and 2009-2010. (SAMHSA, 2014) In this case, zolpidem is not indicated. This is secondary to the prolonged duration of use. As such, the request is not medically necessary.

**One adjustable bed:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Low Back - Lumbar & Thoracic (Acute & Chronic) (7/17/15).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic)/Mattress selection.

**Decision rationale:** The request is for a hospital bed and specialized mattress. The official disability guidelines state the following regarding this topic: Not recommended to use firmness as sole criteria. In a recent RCT, a waterbed (Aqva) and a body-contour foam mattress (Tempur) generally influenced back symptoms, function, and sleep more positively than a hard mattress, but the differences were small. The dominant problem in this study was the large amount of dropouts. The predominant reason for dropping out before the trial involved the waterbed, and there was some prejudice towards this type of mattress. The hard mattress had the largest amount of test persons who stopped during the trial due to worsening LBP, as users were more likely to

turn around in the bed during the night because of pressures on protruding body parts. (Bergholdt, 2008) Another clinical trial concluded that patients with medium-firm mattresses had better outcomes than patients with firm mattresses for pain in bed, pain on rising, and disability; a mattress of medium firmness improves pain and disability among patients with chronic non-specific low-back pain. (Kovacs, 2003) There are no high quality studies to support purchase of any type of specialized mattress or bedding as a treatment for low back pain. Mattress selection is subjective and depends on personal preference and individual factors. On the other hand, pressure ulcers (e.g., from spinal cord injury) may be treated by special support surfaces (including beds, mattresses and cushions) designed to redistribute pressure. (McInnes, 2011) As stated above, there are no high quality studies to support the use of a specialized bed or mattress for the treatment of low back pain. There is no documentation of a pressure ulcer seen. In this case, the request is not supported by the guidelines. As such, a specialized hospital bed or mattress is not medically necessary.