

<b>Case Number:</b>	CM15-0194419		
<b>Date Assigned:</b>	10/08/2015	<b>Date of Injury:</b>	01/17/2013
<b>Decision Date:</b>	12/10/2015	<b>UR Denial Date:</b>	09/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2015

### 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 21 year old male, who sustained an industrial injury on January 17, 2015. He reported injury to his back and right knee. The injured worker was currently diagnosed as having lumbar strain and right knee strain. Treatment to date has included diagnostic studies and medications. On August 6, 2015, the injured worker complained of a flare up of low back pain on 08-03-2015 and 08-04-2015, rating the pain as an 8-9 on a 1-10 pain scale. The pain was noted to be so severe that he was in bed for most of the day. During the flare up, he also reported insomnia, sleeping approximately two hours at night. On the day of exam, he reported low back pain, right knee pain and insomnia secondary to chronic pain. Norco was noted to help mitigate his pain but he cannot take it when he is working. He uses his Ibuprofen medication while at work. The treatment plan included Ambien, lumbar support brace, massage therapy, Ibuprofen, Norco, Cyclobenzaprine and a follow-up visit. On September 9, 2015, utilization review denied a request for Ambien 5mg #15, Cyclobenzaprine 7.5mg #30 and Ibuprofen 800mg #60. A request for Norco 10-325mg #30 was modified to Norco 10-325mg #20.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ambien 5 mg Qty 15:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Zolpidem (Ambien); Insomnia treatment.

**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 counter-therapeutic 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.

**Cyclobenzaprine 7.5 mg Qty 30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

**Ibuprofen 800 mg Qty 60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**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)/NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (Van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back

pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009) As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is not supported. This is secondary to inadequate documentation of functional improvement benefit seen. Also, the duration of use places the patient at risk for gastrointestinal and cardiovascular side-effects. In addition, it is known that use of NSAIDs delays the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not medically necessary.

**Norco 10/325 mg Qty 30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification), Opioids, criteria for use, Opioids, specific drug list, Weaning of Medications.

**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. Functional improvement means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit and a reduction in the dependency on continued medical treatment. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome. As such, the request is not medically necessary.