

<b>Case Number:</b>	CM15-0143372		
<b>Date Assigned:</b>	08/04/2015	<b>Date of Injury:</b>	04/26/2001
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	06/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/23/2015

### 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: Preventive Medicine, Occupational 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 48-year-old male who sustained an industrial injury on April 26, 2001, incurring back injuries. He was diagnosed with lumbosacral root lesions, cervical root lesions, sleep related leg cramps and tarsal tunnel syndrome. Treatment has included medications. The most current provider's progress note, dated June 8, 2015, reported the injured worker complained of persistent low back pain and loss of feeling in the right leg and foot. Exam showed dorsolumbar tenderness and spasms with limited flexion and extension, sacroiliac tenderness on the right, lower extremity reflexes +1/4 and normal lower extremity motor exam. The treatment plan that was requested for authorization included prescriptions for Norco, Zanaflex, Ambien, Tramadol and Lyrica.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #150 with 3 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-9, Chronic Pain Treatment Guidelines Medications for chronic pain; Opioids Page(s): 60-1, 74-96.

**Decision rationale:** Hydrocodone-Acetaminophen (Norco) is a mixed medication made up of the short acting, opioid, hydrocodone, and acetaminophen, better known as Tylenol. It is recommended for moderate to moderately severe pain with usual dosing of 5-10 mg hydrocodone per 325 mg of acetaminophen taken as 1-2 tablets every 4-6 hours. Maximum dose according to the MTUS is limited to 4 gm of acetaminophen per day, which is usually 60-120 mg/day of hydrocodone. According to the MTUS opioid therapy for control of chronic pain, while not considered first line therapy, is considered a viable alternative when other modalities have been tried and failed. Success of this therapy is noted when there is significant improvement in pain or function. The risk with this therapy is the development of addiction, overdose and death. The pain guidelines in the MTUS directly address this issue and have outlined criteria for monitoring patients to allow for safe use of chronic opioid therapy. At this point in the care of this patient the safe use of chronic opioid therapy is at question. There is no documentation of a patient opioid use contract, comments on the effectiveness or side effects from opioid therapies or screening for addiction or aberrant behaviors/medication misuse. The safe use of chronic opioid therapy should have this documentation. Medical necessity for the continued safe use of this medication has not been established. The request is not medically necessary.

**Zanaflex 4mg #60 with 3 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Muscle relaxants for pain Page(s): 63- 6.

**Decision rationale:** Tizanidine (Zanaflex) is a central-acting sedating muscle relaxant used to relax spastic muscles and relieve pain caused by strains, sprains, and other musculoskeletal conditions. This class of medications can be helpful in reducing pain and muscle tension thus increasing patient mobility but, as a group, are recommended for short-term use only, as their efficacy appears to diminish over time. In fact, chronic use of these medications may reduce a patient's motivation or ability to increase activity and thus hinder return to function. The MTUS recommends use of tizanidine for muscle spasms and/or pain relief associated with chronic low back pain. It also notes that muscle relaxants are considered no more effective at pain control than non-steroidal anti-inflammatory medication (NSAIDs) and there is no study that shows combination therapy of NSAIDs with muscle relaxants has a demonstrable benefit. This patient has been on muscle relaxant therapy for over 6 months along with NSAID therapy. There is no documentation of the effectiveness of this therapy nor that muscle relaxants are being/have been used for an intermittent or as needed treatment. The patient continues to have muscle spasms on repeat exams despite taking these medications. Medical necessity for continued use of muscle relaxants as a group or Zanaflex specifically has not been established. The request is not medically necessary.

**Ambien 10mg 30 with 3 refills:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Schutte-Rodin S, et al. Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults. J Clin Sleep Med 2008; 4(5): 487-504.

**Decision rationale:** Zolpidem (Ambien, Ambien CR) is a short-acting benzodiazepine receptor agonist medication. It is indicated for short-term (usually about two to six weeks) treatment of insomnia. It is very effective in initiating sleep but has not adequately demonstrated effectiveness in maintaining sleep, unless delivered in a controlled-release (CR) form. Long-term use of zolpidem is associated with drug tolerance, drug dependence, rebound insomnia, and CNS-related adverse effects. Insomnia is defined by the American Academy of Sleep Medicine (AASM) as the subjective perception of difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity for sleep, and that results in some form of daytime impairment. It is the most prevalent sleep disorder in the general population. It requires a full work-up to understand its etiology and to direct therapy. The AASM guideline recommends any pharmacologic treatment for chronic insomnia be accompanied by cognitive and behavioral treatments. Additionally, it recommends use of benzodiazepines or benzodiazepine receptor agonist medications be used short term followed by other sedating agents such as sedating antidepressants and atypical anti-psychotics. This patient has disordered sleep supposedly from nocturnal leg movements that has been attributed to his industrial injury yet a full evaluation for the etiology for this problem has not been done. He has been taking zolpidem for longer than 6 weeks and is still experiencing frequent nighttime awakenings. The medical necessity for continued use of this medication has not been established. The request is not medically necessary.

**Tramadol 200mg #30 with 2 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Medications for chronic pain; Opioids Page(s): 60-1, 74-96.

**Decision rationale:** Tramadol is a narcotic pain reliever with mu-receptor opioid agonist activity and is used to treat moderate to severe pain. Tramadol ER is an extended release formulation of this medication. Appropriate dosing should not exceed 400 mg/day and it should be used with caution in any patient taking Selective Serotonin Reuptake Inhibitors (SSRI) as together they may cause a potentially fatal condition known as Serotonin Syndrome. There are no studies showing effective use of this medication for chronic pain that lasts greater than 3 months. However, the MTUS describes use of narcotics for control of chronic pain. Even though this is not considered a first-line therapy, the chronic use of narcotics is a viable alternative when other therapeutic modalities have been tried and failed. Success of this therapy is noted when there is significant improvement in pain or function. The risk with this therapy is the development of addiction, overdose or death. The pain guidelines in the MTUS directly address this issue and have criteria for the safe use of chronic opioids. At this point in the care of this patient the safe use of chronic opioid therapy is at question. There is no documentation of a patient opioid use contract, comments on the effectiveness or side effects from opioid

therapies or screening for addiction or aberrant behaviors/medication misuse. The safe use of chronic opioid therapy should have this documentation. Medical necessity for the continued safe use of this medication has not been established. The request is not medically necessary.

**Lyrica 100mg #60 with 3 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 16-22.

**Decision rationale:** Lyrica (pregabalin) is classified as an anti-epileptic drug (AED) indicated in the treatment of epilepsy, anxiety, mood disorders, benign motor tics and neuropathic pain from either trigeminal neuralgia or diabetic neuropathy etiologies. Presently, there are no good clinical trials for use of this type of medication for treating axial low back pain but as this type of pain may have a neuropathic origin suggests it may be effective for this condition, too. The MTUS recommends use of anti-epileptic drugs as a first line therapy for neuropathic pain from nerve damage and further describes the goal of therapy to be when the pain decreases 30-50% or more and the patient's level of functioning improves. This patient was just recently started on Lyrica for treatment of chronic neuropathic pain. There was no description in the medical records provided for review that the medication has relieved or lessened the patient's symptoms. The MTUS requires evidence of medication effectiveness as noted above. Medical necessity for continued use of this medication has not been established. The request is not medically necessary.