MAXIMUS Federal Services

| Case Number: | CM15-0020803 | | |
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| Date Assigned: | 02/10/2015 | Date of Injury: | 07/06/2012 |
| Decision Date: | 03/27/2015 | UR Denial Date: | 01/07/2015 |
| Priority: | Standard | Application Received: | 02/04/2015 |

## 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 54 year old female, who sustained an industrial injury on 07/06/2012. She has reported low back pain. The diagnoses have included lumbago; status post lumbar fusion; and lumbar post-laminectomy syndrome. Comorbid conditions include obesity (BMI 33.6). Treatment to date has included medications, bracing, and surgical intervention. Currently, the IW complains of persistent low back pain, lower extremity pain, neck pain, and right forearm pain; pain is rated at 10/10 on the visual analog scale without medications, and rated 8/10 with medications; and the pain medication helps her with activities of daily living and activity at home. A progress report from the treating physician, dated 12/12/2014, reported objective findings to include tenderness and spasms in the lumbar paraspinal muscles; stiffness with motion of the spine and decreased range of motion; and tenderness to the lumbar facet joints. The treatment plan included prescriptions for Norco, Tramadol, Zolpidem, and Omeprazole; and continue home exercise programOn 01/07/2015 Utilization Review non-certified a prescription for Norco 10/325 mg #60; a prescription for Tramadol 50 mg #30; a prescription for Zolpidem 5 mg #30; and a prescription for Omeprazole 20 mg #30. The MTUS and the ODG were cited. On 01/21/2015, the injured worker submitted an application for IMR for review of Norco 10/325 mg #60; Tramadol 50 mg #30; Zolpidem 5 mg #30; and Omeprazole 20 mg #30.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg # 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation CA MTUS: 2010 Revision, Web EditionOfficial Disability Guidelines, Web Edition

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-9,Chronic Pain Treatment Guidelines 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 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. If treating chronic low back pain, opioids effectiveness is limited to short-term pain relief (up to 16 weeks) as there is no evidence of long-term effectiveness. It is known that long-term use of opioids is associated with hyperalgesia and tolerance. 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 prevent iatrogenic morbidity and mortality. The provider appears to be following this recommendation although one medical record did note that the patient has asked other providers to prescribe her pain medications which is a violation of the pain prescribing agreement recommended by the MTUS. The patient has tried but did not tolerate first-line pain medications recommended by the MTUS (multiple antidepressants and even an antiepileptic medication). Her medications do lower her pain levels and allow for improved activities of daily living, however, she is showing signs of hyperalgesia in that her level of pain continues to increase at each visit. At her last visit her level of pain was 10/10. Additionally, the patient is on two short acting opioids (Tramadol and Norco). To prevent confusion in medications and improve patient safety the provider should only prescribe one short-acting opioid if opioid therapy is to continue. Drug-seeking behavior needs to be re-evaluated by her provider. In summary, the patient is on long-term opioid therapy (over the 16 week limit recommended by the MTUS) with two short-acting opioid medications yet is developing signs of drug-seeking behavior and hyperalgesia. Patient safety with continued use of this medication is a real concern. Medical necessity for continued use of Norco has not been established.

**Tramadol 50mg # 30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation CA MTUS: 2010 Revision, Web EditionOfficial Disability Guidelines, Web Edition

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

**Decision rationale:** Ultram (tramadol) an opioid pain medication used to treat moderate to moderately severe pain with usual dosing every 6-8 hours. It acts by binding to the -opioid receptor but it also inhibits the reuptake of serotonin and norepinephrine. Because of this second activity it must be used cautiously in patients taking serotonin reuptake inhibitor medications as the combined medications may precipitate a life-threatening serotonin syndrome event. Studies have shown the effectiveness of this medication to control pain for up to three months but there are no long-term studies available showing effectiveness of chronic use. 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. If treating chronic low back pain, opioids effectiveness is limited to short-term pain relief (up to 16 weeks) as there is no evidence of long-term effectiveness. It is known that long-term use of opioids is associated with hyperalgesia and tolerance. 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 prevent iatrogenic morbidity and mortality. The provider appears to be following this recommendation although one medical record did note that the patient has asked other providers to prescribe her pain medications which is a violation of the pain prescribing agreement recommended by the MTUS. The patient has tried but did not tolerate first-line pain medications recommended by the MTUS (multiple antidepressants and even an antiepileptic medication). Her medications do lower her pain levels and allow for improved activities of daily living, however, she is showing signs of hyperalgesia and tolerance in that her level of pain continues to increase at each visit. At her last visit her level of pain was 10/10. Additionally, the patient is on two short acting opioids (Tramadol and Norco). To prevent confusion in medications and improve patient safety the provider should only prescribe one short-acting opioid if opioid therapy is to continue. Drug-seeking behavior needs to be re-evaluated by her provider. In summary, the patient is on long-term opioid therapy (over the 16 week limit recommended by the MTUS) with two short-acting opioid medications yet is developing signs of drug-seeking behavior and hyperalgesia and drug tolerance. Patient safety with continued use of this medication is a real concern. Medical necessity for continued use of tramadol has not been established.

**Zolpidem:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation CA MTUS: 2010 Revision, Web EditionOfficial Disability Guidelines, Web Edition

**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, 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, 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 antipsychotics. This patient has been taking zolpidem for longer than 6 weeks and is still experiencing frequent nighttime awakenings. A full evaluation for the etiology for her chronic insomnia has not been done. The medical necessity for continued use of this medication has not been established.

**Omeprazole 20mg # 30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**Decision rationale:** Omeprazole is classified as a proton pump inhibitor and recommended for treatment of dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, laryngopharyngeal reflux, and Zollinger Ellison syndrome. The MTUS recommends its use to prevent dyspepsia or peptic ulcer disease secondary to longer-term use of non-steroidal anti-inflammatory medications (NSAIDs). Even though dyspepsia is also a known side effect of opioid medications the MTUS does not address its use to prevent or treat dyspepsia caused by long-term use of opioids. Since this patient is not complaining nor diagnosed with any symptoms of dyspepsia, peptic ulcer disease, gastroesophageal reflux disease, laryngopharyngeal reflux, or Zollinger Ellison syndrome other than one episode of dyspepsia associated with use of Cymbalta (even while taking omeprazole) and since there is no present use of NSAIDs nor any indication for use of chronic opioid therapy the medical necessity for continued use of omeprazole has not been established.