

<b>Case Number:</b>	CM14-0054994		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	07/19/1999
<b>Decision Date:</b>	08/26/2014	<b>UR Denial Date:</b>	04/04/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/24/2014

### 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. The expert reviewer is Board Certified in Emergency Medicine and is licensed to practice in New York. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient is a 58-year-old female who was injured on July 19, 1999. The patient continued to experience anxiety and entire body pain. Physical examination was notable for muscle spasm and tenderness over the facet joints. Diagnoses included suicidal tendency, anxiety, chronic pain in the neck, back, and shoulder, and C7-8 radiculopathy. Treatment included medications, physical therapy, and steroid injections. Requests for authorization for Restoril 15 mg # 30 with one refill, Restoril 30 mg # 30 with one refill, Lunesta 2 mg # 30 with one refill, and Norco 10/325 mg #120 with one refill were submitted for consideration.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Restoril 15mg # 15 1 Refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines. Decision based on Non-MTUS Citation Official Disability Guidelines: Insomnia.

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

**Decision rationale:** Restoril is the medication Temazepam, an FDA-approved benzodiazepine for sleep maintenance insomnia. This medication is only recommended for short-term use due to risk of tolerance, dependence, and adverse events (daytime drowsiness, anterograde amnesia, next-day sedation, impaired cognition, impaired psychomotor function, and rebound insomnia). Benzodiazepines have been associated with sleep-related activities such as sleep driving, cooking and eating food, and making phone calls (all while asleep). Particular concern is noted for patients at risk for abuse or addiction. Withdrawal occurs with abrupt discontinuation or large decreases in dose. In this case the patient had been taking the medication since at least October 2013. The duration of treatment surpasses the recommended short-term duration. In addition the patient continues to experience difficulty with sleep. Therefore, the Restoril 15mg # 15 1 Refill is not medically necessary.

**Restoril 30mg #15 1 Refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines. Decision based on Non-MTUS Citation Official Disability Guidelines: Insomnia.

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

**Decision rationale:** Restoril is the medication Temazepam, an FDA-approved benzodiazepine for sleep maintenance insomnia. This medication is only recommended for short-term use due to risk of tolerance, dependence, and adverse events (daytime drowsiness, anterograde amnesia, next-day sedation, impaired cognition, impaired psychomotor function, and rebound insomnia). Benzodiazepines have been associated with sleep-related activities such as sleep driving, cooking and eating food, and making phone calls (all while asleep). Particular concern is noted for patients at risk for abuse or addiction. Withdrawal occurs with abrupt discontinuation or large decreases in dose. In this case the patient had been taking the medication since at least October 2013. The duration of treatment surpasses the recommended short-term duration. In addition the patient continues to experience difficulty with sleep. The request for Restoril 30mg #15 1 Refill is not medically necessary.

**Lunesta 2mg #30 1 refill:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Insomnia Official Disability Guidelines: Pain( Acute & Chronic ).

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

**Decision rationale:** Insomnia treatment should be based on etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of

sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Lunesta is the non-benzodiazepine sedative hypnotic medication, Eszopicolone, recommended as first line medication for insomnia. It is a benzodiazepine-receptor agonist which works by selectively binding to type-1 benzodiazepine receptors in the CNS. All of the benzodiazepine-receptor agonists are schedule IV controlled substances, which mean they have potential for abuse and dependency. It is the only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. A randomized, double blind, controlled clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the control group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period. Side effects are dry mouth, unpleasant taste, drowsiness, dizziness. Sleep-related activities such as driving, eating, cooking and phone calling have occurred. Withdrawal may occur with abrupt discontinuation. Dosing is 1-2 mg for difficulty falling asleep and 2-3 mg for sleep maintenance. The drug has a rapid onset of action. In this case the patient had been using the medication and was still experiencing sleep problems. The Lunesta 2mg #30 1 refill is not medically necessary.

**Norco 10/325mg #120 x 1 Refill:** 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 Pain Interventions and Guidelines , page(s) 74-96 Page(s): 74-96.

**Decision rationale:** Norco is the compounded medication containing hydrocodone and acetaminophen. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short term use if first-line options, such as acetaminophen or NSAIDS have failed. Opioids may be a safer choice for patients with cardiac and renal disease than antidepressants or anticonvulsants. Acetaminophen is recommended for treatment of chronic pain & acute exacerbations of chronic pain. Acetaminophen overdose is a well-known cause of acute liver failure. Hepatotoxicity from therapeutic doses is unusual. Renal insufficiency occurs in 1 to 2% of patients with overdose. The recommended dose for mild to moderate pain is 650 to 1000 mg orally every 4 hours with a maximum of 4 g/day. In this case the patient had been receiving Norco since at least October 2013 and had not obtained analgesia. There is no documentation that the patient has signed an opioid contract or participating in urine drug testing. Criteria for long-term opioid use have not been met. The Norco 10/325mg #120 x 1 Refill is not medically necessary.