

<b>Case Number:</b>	CM15-0112090		
<b>Date Assigned:</b>	06/18/2015	<b>Date of Injury:</b>	04/26/1999
<b>Decision Date:</b>	07/17/2015	<b>UR Denial Date:</b>	05/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/10/2015

### 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: New Jersey, Alabama, California  
 Certification(s)/Specialty: Neurology, Neuromuscular 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 39 year old male, who sustained an industrial injury on 4/26/99. He reported pain in his neck and lower back. The injured worker was diagnosed as having lumbar radiculopathy, cervical radiculitis and lumbar strain. Treatment to date has included psychiatric treatments. Current medications include Vicodin ES and Restoril since at least 12/17/14. On 2/23/15, the injured worker reported sleeping better but still having pain. As of the PR2 dated 5/13/15, the injured worker reports no change in pain. No objective findings noted in the case file. The treating physician requested to continue Vicodin ES 7.5/300mg #90 x 5 refills and Restoril 30mg #30 x 5 refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Vicodin ER (extended release) 7.5/300 mg Qty 90 with 5 refills: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): 179.

**Decision rationale:** According to MTUS guidelines, ongoing use of opioids should follow specific rules: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy; (b) The lowest possible dose should be prescribed to improve pain and function; (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. Vicodin is a short acting opioid recommended for a short period of time in case of a breakthrough pain or in combination with long acting medications in case of chronic pain. There is no clear evidence of a breakthrough of back pain. There is no documentation of pain and functional improvement with previous use of Narcotics. Therefore, the request for Vicodin ER 7.5/300mg #90 with 5 refills is not medically necessary.

**Restoril 30 mg Qty 30 with 5 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

**Decision rationale:** According to ODG guidelines and in the treatment of insomnia section. Recommend that treatment be based on the etiology, with the medications recommended below. See Insomnia. 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. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; and (d) Next-day functioning. Pharmacologic Treatment: There are four main categories of pharmacologic treatment: (1) Benzodiazepines; (2) Non-benzodiazepines; (3) Melatonin & melatonin receptor agonists; and (4) Over-the-counter medications. The majority of studies have only evaluated short-term treatment (i.e., 4 weeks) of insomnia; therefore, more studies are necessary to evaluate the efficacy and safety of treatments for long-term treatment of insomnia. In 2007, the FDA requested that manufacturers of all sedative-hypnotic drugs strengthen product labeling regarding risks (i.e., severe allergic reactions and complex sleep-related behaviors, such as sleep driving). It is recommended that treatments for insomnia should reduce time to sleep onset, improve sleep maintenance,

avoid residual effects and increase next-day functioning. (Morin, 2007) (Reeder, 2007) (1)

Benzodiazepines: FDA-approved benzodiazepines for sleep maintenance insomnia include estazolam (ProSom), flurazepam (Dalmane), quazepam (Doral), and temazepam (Restoril). Triazolam (Halcion) is FDA-approved for sleep-onset insomnia. These medications are 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). These drugs 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. Decrease slowly and monitor for withdrawal symptoms. Benzodiazepines are similar in efficacy to benzodiazepine-receptor agonists; however, the less desirable side-effect profile limits their use as a first-line agent, particularly for long-term use. According to MTUS guidelines, benzodiazepines are not recommended for long-term use for pain management because of unproven long-term efficacy and because of the risk of dependence. Most guidelines limit their use to 4 weeks. The patient did use this medication for a longtime without any evidence of functional improvement. In addition, on May 14, 2014, Restoril was not certified. Therefore, the prescription of RESTORIL 30MG #30 with 5 refills is not medically necessary