

<b>Case Number:</b>	CM15-0130160		
<b>Date Assigned:</b>	07/16/2015	<b>Date of Injury:</b>	07/25/2006
<b>Decision Date:</b>	08/13/2015	<b>UR Denial Date:</b>	06/25/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/06/2015

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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:

This injured worker is a 50 year old male, who reported an industrial injury on 7/25/2006. His diagnoses, and or impression, were noted to include: lumbar disc displacement without myelopathy; lumbar disc degeneration; sciatica; and disorders of the sacrum. No current imaging studies were noted. His treatments were noted to include medication management; and rest from work. The progress notes of 5/4/2015 reported complaints of lower back pain due to spondylosis and sciatica in both legs, and described trembling and the feeling of fire in both legs every night. He reported his pain and symptoms were made worse with activity and change in the weather; made better with warmer weather, rest and medication; and that his Norco was switched to Hyalingia. Objective findings were noted to include complaints of: severe fatigue, headaches, pain in his neck, a cough, heartburn, abdominal pain, itchy skin, balance problems, and memory loss; no acute distress; and tenderness in the lumbar spine with spasms, guarding and positive bilateral straight leg raise. The physician's requests for treatments were noted to include Rozerem at bedtime.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Rozerem 8 mg, thirty count:** Upheld

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

**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:** Rozerem is a melatonin-receptor agonist. ODG states "Recommend that treatment be based on the etiology, with the medications recommended below. See also Insomnia. For more detail on Insomnia treatment, see the Mental Chapter. 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; & (d) Next-day functioning. Pharmacologic Treatment: There are four main categories of pharmacologic treatment: (1) Benzodiazepines; (2) Non-benzodiazepines; (3) Melatonin & melatonin receptor agonists; & (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) Melatonin-receptor agonist: Ramelteon (Rozerem) is a selective melatonin agonist (MT1 and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential). One systematic review concluded that there is evidence to support the short-term and long-term use of ramelteon to decrease sleep latency; however, total sleep time has not been improved. (Reynoldson, 2008) (Zammit, 2007) Ramelteon is not a controlled substance. Side effects: CNS depression, somnolence, dizziness, fatigue, abnormal thinking and bizarre behavior have occurred. Use with caution in patients with depression, hepatic impairment, and respiratory conditions such as COPD or sleep apnea. Dosing: 8mg within 30 minutes of bedtime; recommended for short-term (7 - 10 days) use only." The medical documentation provided indicate this patient has been utilizing Rozerem in excess of guideline recommendations. The treating physician has not provided documentation of objective functional improvement with the use of this medication. As such, the request for Rozerem 8 mg, thirty count is not medically necessary.