

Case Number:	CM15-0021773		
Date Assigned:	02/11/2015	Date of Injury:	05/08/2008
Decision Date:	03/31/2015	UR Denial Date:	01/21/2015
Priority:	Standard	Application Received:	02/05/2015

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, Michigan, 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:

This 64 year old female sustained an industrial injury on 5/8/08. She subsequently reports chronic low back pain. Diagnoses include lumbar radiculopathy and sacroiliitis. Prior diagnostic tests include x-rays, MRIs and nerve conduction studies. Treatment to date has included work restrictions and prescription pain medications. On 1/21/15, Utilization Review non-certified a request for Meds x2 Rozerem 8mg Tab QTY: 30. The Meds x2 Rozerem 8mg Tab QTY: 30 was denied based on MTUS Chronic Pain and ODG guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Meds x2 Rozerem 8mg Tab QTY: 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (chronic) updated 12/31/2014

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Melatonin <http://www.odg-twc.com/index.html>

Decision rationale: According to ODG guidelines, "recommended for delayed sleep phase syndrome and rapid eye movement sleep behavior disorders. There is also some suggestion that it can have an analgesic effect, but current research is largely in the experimental phases. Melatonin for sleep disorders: See Insomnia treatment. Melatonin appears to reduce sleep onset latency to a greater extent in people with delayed sleep phase syndrome than in people with insomnia. Delayed sleep phase syndrome is characterized by late sleep onset and wake up time. It results in late wake up time, resulting in excessive daytime sleepiness, insomnia and daytime functional impairment. This may indicate that this substance "re-sets" the endogenous circadian pacemaker rather than as a direct action of somnogenic structures of the brain. Individuals with delayed sleep phase syndrome are distinguished from individuals with insomnia by the presence of circadian abnormality. (AHRQ, 2004) (van Geijlswijk, 2010) (Brzezinski, 2005) Melatonin is also used for treatment of rapid eye movement sleep behavior disorder. This is characterized with motor activity during sleep, acting out of dreams, and polysomnography showing increased muscle tone. (Ramar, 2013) (McGrane, 2014) There is no evidence that melatonin is effective in treating secondary sleep disorders accompanying sleep restriction, such as jet lag and shiftwork disorder. The literature reporting treatment of chronic insomnia disorder with melatonin remains inconclusive. (Ferguson, 2010) (Buscemi, 2006) (Buscemi, 2005) (Ferracioli-Oda, 2013) Available formulations: Melatonin is available over-the-counter as well as melatonin receptor agonists: ramelteon (Rozerem); agomelatine (Valdoxan, Melitor, Thymanax); tasimelteon (Hetlioz). Melatonin for pain treatment: There are also experimental and clinical data supporting an analgesic role of melatonin. This appears to depend, in part, on specific melatonin receptors. It is also hypothesized that improved sleep may reduce anxiety and subsequently improve pain. Pain states studied include fibromyalgia, irritable bowel syndrome, migraines and for use in surgical procedures. (Wilhelmsen, 2011)(1) In a recent randomized controlled trial of 63 females with fibromyalgia, melatonin in a dose of 10 mg alone or associated with amitriptyline (25 mg with the same dose of melatonin) versus amitriptyline alone was evaluated. There were significant improvements in VAS, numerical pain scale, Fibromyalgia Impact Questionnaire, and heat pain threshold in the groups on melatonin, with the most significant improvement in the group on the combined treatment. (de Zquette, 2014) (2) A similar study was performed on fibromyalgia patients on fluoxetine who were given adjunct melatonin with a significant decrease noted in the Fibromyalgia Impact Questionnaire. (Hussain, 2011)"There is no documentation that the patient is suffering from sleep issues and the need for Rozerem is unclear. Therefore, the request for Rozerem is not medically necessary.