

<b>Case Number:</b>	CM14-0034660		
<b>Date Assigned:</b>	06/20/2014	<b>Date of Injury:</b>	02/28/2011
<b>Decision Date:</b>	11/19/2014	<b>UR Denial Date:</b>	03/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/20/2014

### 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 Occupational Medicine, and is licensed to practice in California. 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 applicant is a represented ( ) employee who has filed a claim for major depressive disorder, generalized anxiety disorder, insomnia, chronic low back pain, and chronic pain syndrome reportedly associated with an industrial injury of February 28, 2011. In a Utilization Review Report dated March 11, 2014, the claims administrator approved a request for Cymbalta while denying a request for Rozerem. Non-MTUS ODG guidelines were invoked to deny Rozerem. The applicant's attorney subsequently appealed. In a May 30, 2014 progress note, the applicant reported ongoing complaints of low back pain, myofascial pain syndrome, and insomnia secondary to pain. The applicant was apparently working modified duty with medications. The applicant had recently completed acupuncture, it was acknowledged. MS Contin, Neurontin, Cymbalta, and Rozerem were endorsed. It was suggested that the applicant was using Rozerem as a sleep aid and/or for depressive symptoms. In an April 25, 2014 progress note, the applicant was again described as working modified duty. The applicant stated that her sleep was poor without usage of Rozerem.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Continued use of Rozerem 8 MG:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management Page(s): 7. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Sleep Disorder Review of Ramelteon in the Treatment of Sleep Disorders, Neubauer, February 2008

**Decision rationale:** While the MTUS does not address the topic, page 7 of the MTUS Chronic Pain Medical Treatment Guidelines does stipulate that an attending provider incorporate some discussion of medication efficacy into his choice of recommendations. In this case, the attending provider has posited that ongoing usage of Rozerem, a melatonin agonist, has proven effectual as a sleep aid. Several progress notes, referenced above, have suggested that the applicant's sleep issues have been ameliorated following introduction of Rozerem. It is further noted that, per February 2008 review article referenced below, Rozerem (ramelteon) has been approved by the FDA, does not have a direct sedating effect, enhances sleep through effects on sleep regulatory mechanisms within the brain, has no abuse liability, and is not scheduled by the DEA as a controlled substance. The review article goes on to note that the FDA label contains no limitation on how long Rozerem (ramelteon) may be prescribed. In this case, the favorable FDA position on long-term usage of Rozerem, the fact that it is not a scheduled substance, the fact that Rozerem does not have abuse potential and the fact that the applicant has personally reported a favorable response to the same does make a compelling case for continuation of the same. Therefore, the request is medically necessary.