

<b>Case Number:</b>	CM15-0222450		
<b>Date Assigned:</b>	11/18/2015	<b>Date of Injury:</b>	04/04/2011
<b>Decision Date:</b>	12/30/2015	<b>UR Denial Date:</b>	10/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/12/2015

### 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 York, Tennessee

Certification(s)/Specialty: Emergency 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 48 year old female who sustained an industrial injury April 4, 2011. Past history included ACDF (anterior cervical discectomy and fusion). According to a primary treating physician's progress notes dated October 20, 2015, the injured worker presented for follow-up with complaints of fatigue, anxiety and depression. She reported her sleep has improved since starting Melatonin but still has trouble staying asleep. She is also taking 3-4 Tramadol a day for chronic neck and upper limb pain. Current medication included Ambien CR, Flector patch, Melatonin, Diphenhydramine, Tramadol, and Trazodone. The physician documented that on January 27, 2015, the insurance did not approve Ambien, Flector, and Tramadol. Objective findings included; normal gait and posture. Diagnoses are documented as degeneration of cervical intervertebral disc; chronic pain syndrome. Treatment plan included continue with home exercise program and coping techniques learned in Functional Restoration Program. At issue, is the request for authorization for Melatonin and Tramadol. According to utilization review dated October 26, 2015, the requests for Melatonin 5mg #80 with (2) refills and Tramadol 50mg #90 with (2) refills were non-certified.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Melatonin 5mg, #80 with 2 refills:** 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) Pain Chapter Melatonin last updated 10/9/15.

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

**Decision rationale:** Melatonin is 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 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. 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. There is no evidence that melatonin is effective in treating secondary sleep disorders accompanying sleep restriction, such as jet lag and shift work disorder. The literature reporting treatment of chronic insomnia disorder with melatonin remains inconclusive. In this case there is documentation that the patient has been experiencing insomnia for at least one year. The patient does not have delayed onset of sleep but awakens through the night. There is no evidence that melatonin is effective for chronic insomnia. There is no medical indication for use of melatonin. The request is not medically necessary.

**Tramadol 50mg, #90 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** Tramadol is a synthetic opioid affecting the central nervous system. It has several side effects, which include increasing the risk of seizure in patients taking SSRI's, TCA's and other opioids. 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 of function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDS have failed. In this case the patient has been receiving Norco since at least December 2015 and there is no documentation that analgesia has been obtained. In addition there is no documentation that the patient has signed an opioid contract or is participating in urine drug testing. Criteria for long-term opioid use have not been met. The request is not medically necessary.