

Case Number:	CM15-0176025		
Date Assigned:	09/17/2015	Date of Injury:	10/26/2006
Decision Date:	10/28/2015	UR Denial Date:	08/11/2015
Priority:	Standard	Application Received:	09/08/2015

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: California, Arizona, Maryland
 Certification(s)/Specialty: Psychiatry

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 57 year old male who sustained an industrial injury October 26, 2006. According to a primary treating physician's progress report, dated June 24, 2015, the injured worker presented and an evaluation of vital signs were found to be stable. A notation of current medication included Pristiq, Latuda, Nuvigil and Lunesta. Diagnosis documented as major depressive order, mood congruent with incipient psychotic features, in partial remission. A primary treating physician's notes dated July 21, 2015, finds the injured worker presenting for a session appearing quite regressed, angry, and disillusioned and complaining of depression and insomnia. He was told by a human resource person at his work he was not authorized to take Nuvigil and Lunesta as prescribed. He reported, over the course of the July 4th weekend to have stopped all of his medication, which included; Pristiq and Latuda. He agreed not to act out or become hostile. He will try to obtain the prescriptions through private insurance. At issue, is the request for authorization for Nuvigil and Lunesta. According to utilization review dated August 11, 2015, the request for Nuvigil 150mg #30 no refill, one half a tablet Q AM (Rx Date 6-24- 2015 dispensed) is non-certified. The request for Lunesta 3mg #30, no refill Q HS (Rx Date 6- 24-2015 dispensed) is not medical necessary, however, weaning is recommended; (1) month approved for weaning.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nuvigil 150mg #30, one half tablet every AM (Rx Date 6/24/15, dispensed): Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA.gov- Nuvigil.

Decision rationale: MTUS is silent regarding the use of Nuvigil. Per FDA guidelines "Nuvigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA), narcolepsy, or shift work disorder (SWD)." The injured worker does not have diagnosis of excessive sleepiness associated with obstructive sleep apnea, narcolepsy, or shift work disorder for which Nuvigil is currently FDA approved for. It appears that Nuvigil is being used as "Off label" for daytime fatigue and drowsiness. Nuvigil has risk for abuse and dependence. The request for Nuvigil 150mg #30, one half tablet every AM (Rx Date 6/24/15, dispensed) is not medically necessary at this time as he does not have any diagnosis at this time which would warrant use of nuvigil.

Lunesta 3mg #30, every night at bedtime (Rx Date 6/24/15, dispensed): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness & Stress, Eszopiclone (Lunesta).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain/Insomnia Treatment.

Decision rationale: ODG states "Non-Benzodiazepine sedative-hypnotics (Benzodiazepine-receptor agonists) are First-line medications for insomnia. This class of medications includes zolpidem (Ambien and Ambien CR), zaleplon (Sonata), and eszopiclone (Lunesta). Benzodiazepine-receptor agonists work by selectively binding to type-1 benzodiazepine receptors in the CNS. All of the benzodiazepine-receptor agonists are schedule IV controlled substances, which mean they have potential for abuse and dependency." Eszopiclone (Lunesta) has demonstrated reduced sleep latency and sleep maintenance. (Morin, 2007) The only benzodiazepine-receptor agonist FDA approved for use longer than 35 days. A randomized, double blind, controlled clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the control group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period. (Walsh, 2007) Side effects: dry mouth, unpleasant taste, drowsiness, dizziness. Sleep-related activities such as driving, eating, cooking and phone calling have occurred. Withdrawal may occur with abrupt discontinuation. Dosing: 1-2 mg for difficulty falling asleep; 2-3 mg for sleep maintenance. The drug has a rapid onset of action (Ramakrishnan, 2007) According to the guidelines stated above, medications are not recommended for long term treatment of insomnia. Also, Lunesta has potential for abuse,

dependency, withdrawal and tolerance. Thus, the request for Lunesta 3mg #30, every night at bedtime (Rx Date 6/24/15, dispensed) is not medically necessary for ongoing treatment of insomnia.