

Case Number:	CM15-0196675		
Date Assigned:	10/12/2015	Date of Injury:	06/13/2012
Decision Date:	11/23/2015	UR Denial Date:	09/15/2015
Priority:	Standard	Application Received:	10/06/2015

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: California

Certification(s)/Specialty: Preventive Medicine, Occupational 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 on June 13, 2012, incurring upper back and neck injuries. She was diagnosed with cervical degenerative disc disease, cervical stenosis, cervical disc herniation and cervical radiculopathy. Treatment included physical therapy, pain medications, muscle relaxants, sleep aides and anti-anxiety medications, transcutaneous electrical stimulation unit, trigger point injections, surgical spinal interventions, and activity restrictions. Currently, the injured worker complained of severe left upper back pain. A computed tomography of the cervical spine revealed a broken screw in C7. She underwent a redo surgical cervical fusion. She continued with activity restrictions, neck brace and medication management. The treatment plan that was requested for authorization on October 6, 2015, included a prescription for Belsomra 10 mg #30 for insomnia. On September 15, 2015, a request for a prescription for Belsomra was non-certified by utilization review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Belsomra 10mg, 1 tablet by mouth every evening as needed for insomnia, #30: 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), Mental Illness and Stress Chapter - Suvorexant (Belsomra); www.webmd.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress Chapter/Suvorexant (Belsomra) Section.

Decision rationale: The MTUS guidelines do not address the use of Belsomra, therefore, alternative guidelines were consulted. Per the ODG, Belsomra is not recommended as a first-line treatment due to adverse effects. FDA approved a first-in-class insomnia drug suvorexant (Belsomra, Merck) after the manufacturer lowered the dosages to satisfy the agency's safety concerns. Originally the FDA had declined to approve suvorexant until the starting dose for most patients was 10 mg. The agency also said that proposed upper-limit doses of 30 mg for elderly patients and 40 mg for non-elderly patients were unsafe. Suvorexant, an orexin receptor antagonist, is the first drug of its kind to be approved for patients with insomnia. It alters the signaling of orexins, neurotransmitters responsible for regulating the sleep-wake cycle. Drowsiness was the most commonly reported adverse event for clinical trial participants taking suvorexant, which is classified as a Schedule IV controlled substance. In next-day driving tests, both male and female participants who took the 20-mg dose proved to be impaired drivers. The FDA advises physicians to caution patients against next-day driving or other activities requiring full alertness. In this case, there is no evidence of a trial and failure with first-line agents for insomnia. Additionally, the medical records do not indicate that non-pharmacological modalities such as cognitive behavioral therapy or addressing sleep hygiene practices prior to utilizing a pharmacological sleep aid, therefore, the request for Belsomra 10mg, 1 tablet by mouth every evening as needed for insomnia, #30 is determined to not be medically necessary.