

<b>Case Number:</b>	CM15-0186935		
<b>Date Assigned:</b>	09/28/2015	<b>Date of Injury:</b>	02/06/1981
<b>Decision Date:</b>	11/10/2015	<b>UR Denial Date:</b>	09/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/22/2015

### 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 55 year old female, who sustained an industrial injury on 2-6-1981. The medical records indicate that the injured worker is undergoing treatment for complex regional pain syndrome. According to the progress report dated 8-17-2015, the injured worker notes that she is doing "ok." On a subjective pain scale, she rates her pain 6-7 out of 10. The physical examination did not reveal any significant findings. The current medications are Methadone, Percocet, Baclofen, Oxycodone, Zyprexa, and Zolpidem. Treatments to date include medication management, stimulator, and stellate ganglion block. Work status is described as permanently disabled. The original utilization review (9-18-2015) had non-certified a request for Belsomra.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**45 tablets of Belsomra 20 mg: 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), Treatment Index, 13th Edition (Web), 2015, Mental Health and Illness, Suvorexant (Belsomra).

**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 Suvorexant (Belsomra).

**Decision rationale:** Suvorexant (Belsomra): 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 nonelderly 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. (FDA, 2014) The injured worker has been diagnosed with complex regional pain syndrome. According to the most recent progress report available for review dated 8-17-2015, she reported that that she was doing "ok" and rated her pain 6-7 out of 10. She was being prescribed Methadone, Percocet, Baclofen, Oxycodone, Zyprexa, and Zolpidem. She is being prescribed Zolpidem for sleep, the report does not provide any details of the type of sleep disturbance being experienced by her and there is no mention of the medication Belsomra which is being requested. The request for 45 tablets of Belsomra 20 mg is not medically necessary based on the above information.