

Case Number:	CM15-0207015		
Date Assigned:	10/23/2015	Date of Injury:	10/06/2003
Decision Date:	12/09/2015	UR Denial Date:	09/22/2015
Priority:	Standard	Application Received:	10/20/2015

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: Physical Medicine & Rehabilitation

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 61 year old female, who sustained an industrial injury on 10-6-2003. A review of the medical records indicates that the injured worker is undergoing treatment for chronic pain, cervical radiculopathy, status post cervical spinal fusion, occipital neuralgia, iatrogenic opioid dependency, and dysphagia. On 9-8-2015, the injured worker reported neck pain that radiated down the bilateral upper extremities with numbness constantly in the bilateral upper extremities and frequent muscle weakness, low back pain, ongoing headaches, and insomnia associated with ongoing pain and anxiety, worsened since medications reduced. The Primary Treating Physician's report dated 9-8-2015, noted the injured worker was attempting to wean opiate usage. The physical examination was noted to show the cervical spine with spasms, tenderness, and limited range of motion (ROM). The lumbar spine was noted to have spasms, tenderness to palpation, and significant pain with flexion and extension. Prior treatments have included epidural steroid injections (ESIs) with an allergic reaction. The treatment plan was noted to include a slow weaning of Percocet, a request for authorization for a neurologist evaluation for chronic headaches, continued home exercise program (HEP), and prescriptions for Clonidine, Clorazepate, Fioricet, Gabapentin, Lidoderm patch, Percocet, Senokot-S, Tizanidine, and Vitamin D, with Belsomra, prescribed since at least 8-11-2015, Topiramate, and Fentanyl patches prescribed, and Ambien discontinued. The request for authorization dated 9-16-2015, requested Belsomra 5mg #30. The Utilization Review (UR) dated 9-22-2015, non-certified Belsomra 5mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Belsomra 5mg #30: Overturned

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 (Online version): Insomnia treatment.

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

Decision rationale: The patient was injured on 10/06/13 and presents with neck pain, low back pain, and insomnia. The request is for Belsomra 5 mg #30. The utilization review denial rationale is that "it is not clearly established whether the patient has made attempts at non-pharmacological sleep hygiene." The RFA is dated 08/24/15 and the patient is not currently working. The patient has been taking this medication as early as 08/11/15. ODG Guidelines, Mental & Stress Chapter, 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 patient is diagnosed with chronic pain, cervical radiculopathy, status post cervical spinal fusion, occipital neuralgia, iatrogenic opioid dependency, and dysphagia. The 09/08/15 report states that the patient has "insomnia associated with ongoing pain, associated with anxiety, worsened since medications reduced." On 07/14/15, the patient was prescribed with Ambien which was "beneficial with intended effect as prescribed dose." She began taking Belsomra on 08/11/15. It appears that the patient has tried/failed Ambien and has recently been prescribed Belsomra. The request appears reasonable and within ODG guideline indications. Therefore, the requested Belsomra is medically necessary.