

Case Number:	CM15-0215680		
Date Assigned:	11/05/2015	Date of Injury:	04/30/2008
Decision Date:	12/23/2015	UR Denial Date:	10/21/2015
Priority:	Standard	Application Received:	11/03/2015

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 56-year-old female who sustained an industrial injury on 4-30-2008 and has been treated for headache, neck sprain, right shoulder sprain and adhesive capsulitis, degenerative joint disease of the knee and chronic pain syndrome. On 10-1-2015, the injured worker reported that she had been having "poor sleep due to pain," and that she was putting a pillow under her hands and taking 3 Topirimate to fall asleep. There was no documentation discussing sleep hygiene or other interventions. The visit of 10-8-2015 noted that she was having pain in the neck, right shoulder, and wrist; and, both knees. She characterized pain as burning, aching, throbbing, shooting, tingling, radiating, squeezing, numbing, pressure, deep, and cramping, rated as 8-9 out of 10 and said it was constant. Objective findings on 10-8-2015 showed tremors, neck tenderness with spasm, tenderness over both knees, and right shoulder pain. Documented treatment includes chiropractic therapy, physical therapy, occupational therapy, corticosteroid injections, Orthovisc injections, and she had been treated with Gralise for at least 6 months but discontinued it on 9-1-2015. The physician has recommended counseling and acupuncture. The treating physician's plan of care includes Gabapentin and Belsomra, both which were non-certified 10-21-2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin 300mg #90 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-epilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-epilepsy drugs (AEDs).

Decision rationale: Gabapentin is an anti-epileptic medication. Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and post-herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain and has FDA approval for treatment of post-herpetic neuralgia. Gabapentin appears to be effective in reducing abnormal hypersensitivity, to have anti-anxiety effects, and may be beneficial as a sleep aid. Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, dry mouth, and weight gain. It has been recommended for the treatment of pain from spinal cord injury, fibromyalgia, lumbar spinal stenosis, and chronic regional pain syndrome. Recommended trial period is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. If inadequate control of pain is found, a switch to another first-line drug is recommended. In this case, the patient has been using gabapentin since at least April 2015 and has not obtained adequate pain relief. Switch to another first-line drug is recommended. The request is not medically necessary.

Belsomra 10mg #30 with 1 refill: 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 & Stress.

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) Pain: Insomnia treatment.

Decision rationale: Belsomra is suvorexant, a medication for treatment of insomnia. It is not recommended as a first-line treatment due to adverse effects. Insomnia treatment should be based on etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. FDA approved a first-in-class insomnia drug suvorexant 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. In this case there is no documentation that the patient has had been evaluated for possible causes of sleep disturbance or that trials of other treatments for sleep disturbance have failed. Risk of adverse effects and patient safety is high with this medication. The request is not medically necessary.