

Case Number:	CM15-0112860		
Date Assigned:	06/19/2015	Date of Injury:	12/14/2009
Decision Date:	07/27/2015	UR Denial Date:	06/10/2015
Priority:	Standard	Application Received:	06/11/2015

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: Texas, California

Certification(s)/Specialty: Family Practice

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 62 year old female with an industrial injury dated 12/14/09. Diagnoses are chronic regional pain syndrome of left upper extremity, pain related insomnia, and situational depression/anxiety with possible post traumatic stress disorder. In a progress report dated 5/27/15, the primary treating physician notes the injured worker completed one of her additional psychotherapy sessions today with another provider. Per the psychiatric re-evaluation done 3/17/15, she was diagnosed with major depressive disorder, recurrent, with moderate severity and pain disorder associated with both psychological factors and general medical condition; post traumatic stress disorder, chronic, in partial remission; and sleep disorder due to chronic pain syndrome. She was rated at a Global Assessment of Functioning of 45. Electrodiagnostic studies of her upper extremities on 1/14/14 note moderate carpal tunnel syndrome at bilateral wrists, which shows some interval worsening since the previous study of 11/21/11. She is currently taking Norco 10/325 mg three times a day as needed, Lyrica 100 mg three times a day, Betamethasone 0.05% cream which she uses when she develops skin manifestations of her Complex Regional Pain Syndrome in the left upper extremity. She reports pain, hypersensitivity and allodynia in the left upper extremity, with the occurrence of bruising and open skin lesions during exacerbation. The Norco and Lyrica are necessary to help manage her left upper extremity pain so that she is able to function with activities of daily living. A 40%-50% reduction in pain is noted with medication. The pain is described as 8/10 without medications and 4/10 with medications. With the addition of Lyrica, she has been able to decrease dosing of Norco from 4 times a day to 3 times a day. A urine drug screen was done on 2/25/15, which was consistent with the medication regimen. Objective exam of the left upper extremity notes hyperesthesia extending from the left shoulder to the left elbow and range of

motion in the left shoulder is moderately reduced with forward flexion and abduction. There is allodynia extending from the left elbow to the left hand diffusely. The left wrist and hand are erythematous and swollen. The left hand is significant for contractures of all digits, most prominent being the 4th and 5th digits. She is unable to achieve full extension in all fingers and has moderately reduced flexion of fingers. Adduction of the left thumb is to within 2 centimeters of the hypothenar eminence. Exam of the right upper extremity notes impingement signs are negative in the shoulder, negative Tinel's, and range of motion is normal. There is right wrist tenderness at the palmar aspect and she has difficulty tolerating Tinel's and Phalen's testing due to pain although it was negative. She is averaging 3-4 hours of sleep a night and wakes frequently. Previous treatments include Amitriptyline, a failed trial of Neurontin due to lack of benefit and a stellate ganglion block with an adverse response manifested by respiratory distress. The treatment plan is Belsomra 15 mg #30, Norco, Betamethasone 0.05% topical ointment, and Lyrica, with a planned follow up on 6/30/15. The patient has had urine drug screen on 2/25/15 that was consistent. The medication list include Norco, Neurontin, Amitriptyline and Lyrica. Patient had received 3 sessions of the CBT and psychiatric treatment. Per the note dated 4/14/15 the patient was at 40% psychiatric impairment. Per the note dated 3/24/14 patient had major depressive disorder, and sleep disorder due to chronic pain and disturbed sleep. Patient sustained the injury due to fall from stair. A recent detailed psychiatric evaluation note of a psychiatrist was not specified in the records provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Belsomra 15mg #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, 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 (updated 03/25/15) Suvorexant (Belsomra).

Decision rationale: Request: Belsomra 15mg #30. ACOEM/ODG state guideline does not specifically address this issue. Hence ODG used. Belsomra (suvorexant) is a new sleep drug for treating insomnia. It is a dual orexin receptor antagonist (DORA) that blocks orexin A and orexin B from binding the OXR1 and OXR2 receptors. As per cited guideline "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)" A recent detailed psychiatric evaluation note of a psychiatrist was not specified in the records provided. Treatment of underlying psychiatric conditions contributing to the insomnia was not specified in the records provided. The cited guideline do not recommend Belsomra as a first-line treatment due to adverse effects. Response to first line agents for insomnia was not specified in the records provided. The medical necessity of the request for Belsomra 15mg #30 is not fully established for this patient at this time, based on the records submitted.