

Case Number:	CM15-0187635		
Date Assigned:	09/29/2015	Date of Injury:	11/07/2013
Decision Date:	11/12/2015	UR Denial Date:	09/11/2015
Priority:	Standard	Application Received:	09/23/2015

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:

This is a 55-year-old male patient, who sustained an industrial-work injury on 11-7-13. He sustained the injury due to involved in a head on collision. The diagnoses include recurrent major depressive disorder and insomnia. Per the Medical psychiatric records dated 8-7-15, he had back pain, a bit paranoid, less crying spells now, decreased energy, good appetite, gets anxious due to paranoia of police and sexual side effects-unable to sustain orgasm. He reports episodes of crying without any reason and has a history of traumatic head injury. Per the treating physician, report dated 6-22-15 the patient has not returned to work. Per the note dated 5/8/15, he reported being very paranoid, sleeps only 3-4 hours a night, has feelings of hopelessness about his future, he has lost his career, he has flashbacks from his prison life, he was hypervigilant and anxious at times and feels shaky and sweaty, and he has reported sexual side effects. The physician indicates that Cialis is for the sexual side effects from the medications and the decreased libido is due to the depression. The medications list includes ambien, norco, Viibryd (vilazodone), Xanax, and Nuedexta, Belsomra since at least 4-9-15 (Trazadone was discontinued for sleep) and Cialis since at least 2-12-15. Treatment to date has included pain medication, psyche care, pain management, psychotropic medication management and support therapy. The requested services included Belsomra 10mg #20 and Cialis 20mg #10. The original Utilization review dated 9-11-15 partially certified the request for Belsomra 10mg #20 modified to Belsomra 10mg #11 and non- certified the request for Cialis 20mg #10.

IMR ISSUES, DECISIONS AND RATIONALES

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

Belsomra 10mg #20: 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), Pain Chapter, 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) Chapter : Mental Illness & Stress (updated 09/30/15) Suvorexant (Belsomra).

Decision rationale: Belsomra 10mg #20, Per the cited guidelines, Suvorexant (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 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 cited guidelines do not recommend suvorexant as a first line treatment for insomnia. A failure of other measures for treatment of the patient's insomnia symptoms, including proper sleep hygiene, and medications other than controlled substances, is not specified in the records provided. The medical necessity of Belsomra 10mg #20 is not fully established for this patient at this time given the medical records submitted and the guidelines referenced. The request is not medically necessary.

Cialis 20mg #10: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Thomson Micromedex-FDA labeled indication of cialis-Tadalafil.

Decision rationale: Cialis 20mg #10, Cialis contains tadalafil. Per the Thompson Micromedex guidelines cited below, FDA labeled indication for Tadalafil includes "Benign prostatic hyperplasia, Benign prostatic hyperplasia - Erectile dysfunction, Erectile dysfunction, Pulmonary hypertension." A recent detailed clinical evaluation with a urogenital examination is not specified in the records provided. A detailed evaluation related to erectile dysfunction was not specified in the records provided. Evidence of benign prostatic hyperplasia or pulmonary

hypertension is not specified in the records provided. Response to the previous use of Tadalafil is not specified in the records provided. An ultrasonography report or physical examination documenting BPH is not specified in the records provided. The medical necessity of Cialis 20mg #10 is not medically necessary for this patient.