

Case Number:	CM15-0187410		
Date Assigned:	09/29/2015	Date of Injury:	06/03/2014
Decision Date:	11/10/2015	UR Denial Date:	08/24/2015
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: 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 44 year old male, who sustained an industrial injury on 6-03-2014. The injured worker is being treated for panic disorder with agoraphobia in full remission, major depressive disorder single episode partial remission, and insomnia related to panic disorder and depression. Treatment to date has included modified work and medication management. Per the Primary Treating Physician's Progress Report dated 7-09-2015 the injured worker reported good sleep on 20mg of Belsomra for the first 7 days then his sleep decreased to about 5 hours and feels not well rested in the AM. He was still taking Trazodone 150mg. He reports one panic attack while driving but he was able to continue to drive. His symptoms of depression and anxiety "go up and down" triggered by insomnia or perceived uncontrolled situations. Objective findings included improved attention and concentration. His memory was forgetful and his judgment was fair. Per the medical records dated 6-18-2015 to 7-09-2015 there is no documentation of improvement in symptoms, or efficacy of the prescribed medications. On 4-16-2015 he reported feeling better. "I am more functional, more focused, I have more energy." He reported insomnia was still a problem but he has less severity of depression and less anhedonia. He attends anxiety group and he finds it very helpful, however, there is no documentation regarding the efficacy of the prescribed medications. Work status was modified. The plan of care included medications and cognitive behavioral therapy and authorization was requested for Effexor XR 150mg #60, Belsomra 10mg #30, Wellbutrin XL 300mg #30, Trazodone 50mg #90, monthly medication management and 6 sessions of cognitive behavioral therapy. On 8-24-2015, Utilization Review modified the request for Belsomra 10mg #30 and non-certified the request for Trazodone 50mg #90 and medication management monthly x 6.

IMR ISSUES, DECISIONS AND RATIONALES

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

Belsomra 20mg by mouth at bedtime, #30 with 2 refills: 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), TWC Mental illness & Stress Procedure Summary online Version, updated 03/25/2015.

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: Per ODG, 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) It has been indicated that the injured worker benefited from use of Belsomra for five days after initiation and then the total time of sleep reduced to 5 hours again. The request for a three month supply of Belsomra 20mg by mouth at bedtime, #30 with 2 refills is excessive and not medically necessary based on lack of improvement or maintained stability with this medication. It is to be noted that the UR physician authorized one-month supply of the medication.

Trazodone 50mg #90 with 2 refills (taper off trazodone at the rate of 25mg per week; restart latest effective dose if sleep worsens): 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), TWC Mental illness & Stress Procedure Summary online Version, updated 03/25/2015.

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/ Trazodone (Desyrel).

Decision rationale: Per ODG, Trazodone: Recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. See also Insomnia treatment, where it says there is limited evidence to support its use for insomnia, but it may be an option in patients with coexisting depression. See also Fibromyalgia in the Pain Chapter, where trazodone was used successfully in fibromyalgia. Trazodone was approved in 1982 for the treatment of depression. It is unrelated to tricyclic or tetracyclic anti-depressants and has some action as an anxiolytic. Off-label uses include

alcoholism, anxiety, insomnia, and panic disorder. Although approved to treat depression, the American Psychiatric Association notes that it is not typically used for major depressive disorder. Over the period 1987 through 1996, prescribing trazodone for depression decreased throughout the decade, while off-label use of the drug for insomnia increased steadily until it was the most frequently prescribed insomnia agent. To date, there has been only one randomized, double blind, placebo-controlled trial studying trazodone in primary insomnia. It was observed that relative to placebo, patients reported significant improvement in subjective sleep latency, sleep duration, wake time after sleep onset, and sleep quality with trazodone and zolpidem during week one, but during week two the trazodone group did not differ significantly from the placebo group whereas the zolpidem group demonstrated significant improvement compared to placebo for sleep latency and sleep duration. (Walsh, 1998) The AHRQ Comparative Effectiveness Research on insomnia concludes that trazodone is equal to zolpidem. (AHRQ, 2008) Evidence for the off-label use of trazodone for treatment of insomnia is weak. The current recommendation is to utilize a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. Also worth noting, there has been no dose-finding study performed to assess the dose of trazodone for insomnia in non-depressed patients. Other pharmacologic therapies should be recommended for primary insomnia before considering trazodone, especially if the insomnia is not accompanied by comorbid depression or recurrent treatment failure. There is no clear-cut evidence to recommend trazodone first line to treat primary insomnia. (Mendelson, 2005) The request for Trazodone 50mg #90 with 2 refills (taper off trazodone at the rate of 25mg per week; restart latest effective dose if sleep worsens) is excessive and not medically necessary as the submitted documentation has revealed lack of objective improvement with this medication. The request for another three-month supply is not medically necessary.

Medication management monthly x 6: 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), TWC Mental illness & Stress Procedure Summary online Version, updated 03/25/2015.

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/ Office visits.

Decision rationale: ODG states "Office visits are recommended as determined to be medically necessary. The need for clinical office visit with a health care provider is individualized based upon the review of patient concerns, signs, symptoms, clinical stability and reasonable physician judgment. The determination is also based on what medications the patient is taking, since some medications such as opiates, or medicines such as certain antibiotics, require close monitoring. As patient conditions are extremely varied, a set number of office visits per condition cannot be reasonably established. The determination of necessity for an office visit requires individualized case review and assessment, being ever mindful that the best patient outcomes are achieved with eventual patient independence from health care system through self care as soon as clinically feasible". The injured worker has been diagnosed with panic disorder with agoraphobia in full remission, major depressive disorder single episode partial remission, and insomnia related to panic disorder and depression. He is being prescribed Effexor XR 300 mg, Belsomra 10mg, Wellbutrin XL 300mg and Trazodone 150mg daily. The request for Medication management monthly x 6 is excessive and not medically necessary as the injured worker is not on any medication needing such close monitoring requiring six more office visits at this time.