

Case Number:	CM15-0206148		
Date Assigned:	10/23/2015	Date of Injury:	06/03/2008
Decision Date:	12/10/2015	UR Denial Date:	10/12/2015
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: 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 49 year old male patient who sustained an industrial injury on June 3, 2008. The diagnosis includes status post anterior lumbar discectomy, one level and interbody fusion with placement of anterior lumbar titanium plate and instrumentation fixation system. A recent detail clinical evaluation note is not specified in the records provided. According to the most recent physician's notes dated June 1, 2015, he presented for a regular psychiatric follow-up visit. He reported not doing well the last month; medication was not filled for 9-10 days, feeling depressed, went to daughter's graduation and didn't enjoy it, episodes of anxiety with butterfly sensations in his stomach, felt worthless and useless. He was sleeping for 3-4 hours per night; concentration was poor, appetite erratic, having uncontrollable crying spells. He had no psychomotor agitation or retardation, no suicidal or homicidal ideations. He walked with the assistance of a cane. Current medications included Cymbalta, Seroquel XR, and Nuedexta. Past history included anterior lumbar discectomy, one level and interbody fusion with placement of anterior lumbar titanium plate and instrumentation fixation system in August 2010. Treatment plan included adjustments to medications and will continue with supportive therapy. At issue, is the request for authorization for Xanax and Belsomra. According to utilization review dated October 12, 2015, the requests for Xanax 0.5mg #45 and Belsomra 10mg #30 were non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xanax 0.5mg #45: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Mental Illness & Stress (updated 11/24/15) Benzodiazepine.

Decision rationale: Xanax contains Alprazolam which is a benzodiazepine, an anti-anxiety drug. According to MTUS guidelines Benzodiazepines are "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks...long-term use may actually increase anxiety." In addition per the cited guidelines "Recent research: Use of benzodiazepines to treat insomnia or anxiety may increase the risk for Alzheimer's disease (AD)... Benzodiazepines are little better than placebo when used for the treatment of chronic insomnia and anxiety, the main indications for their use." Prolonged use of an anxiolytic may lead to dependence and does not alter stressors or the individual's coping mechanisms and is therefore not recommended. The response to other measures for insomnia/anxiety is not specified in the records provided. The request for Xanax 0.5mg #45 is not medically necessary or fully established for this patient given the medical records submitted and the guidelines referenced. If it is decided to discontinue this medication, then it should be tapered according to the discretion of the treating provider, to prevent withdrawal symptoms.

Belsomra 10mg #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 (ODG), Mental Illness & Stress - Suvorexant (Belsomra).

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: 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 recommended 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 request for Belsomra 10mg #30 is not medically necessary or fully established for this patient at this time given the medical records submitted and the guidelines referenced.