

Case Number:	CM15-0217081		
Date Assigned:	11/06/2015	Date of Injury:	02/24/1997
Decision Date:	12/21/2015	UR Denial Date:	10/02/2015
Priority:	Standard	Application Received:	11/04/2015

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, Oregon, Washington
 Certification(s)/Specialty: Orthopedic Surgery

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 69 year old female, who sustained an industrial injury on 02-24-1997. The injured worker is currently permanent and stationary. Medical records indicated that the injured worker is undergoing treatment for chronic severe back and left leg pain, epidural fibrosis versus arachnoiditis, left L3-4 and L4-5 lesion, and status post multiple level fusion-hardware removal with severe ongoing pain. Treatment and diagnostics to date has included urine drug screen on 06-03-2015 ("consistent" per 09-23-2015 progress note) and use of medications. Recent medications have included Gralise, Lunesta, Oxycodone, OxyContin, and Senokot. Subjective data (09-23-2015), included low back and leg pain rated 7 out of 10. The treating physician noted that the injured worker's medications are "working well", sleep quality is "poor", and has trouble staying asleep. Objective findings (09-23-2015) included decreased active range of motion to lumbar spine and an antalgic gait with use of 4 prong cane. The request for authorization dated 09-24-2015 requested Oxycodone 15 1 by mouth four times daily #120 as needed for pain, OxyContin, Gralise, trial Belsomra 10mg 1 by mouth at bedtime #30, Linzess, and Lyrica. The Utilization Review with a decision date of 10-02-2015 non-certified the request for Oxycodone 15mg #120 and Belsomra 10mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Oxycodone 15mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain, Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids, specific drug list. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain / Opioids criteria for use.

Decision rationale: According to the CA MTUS/Chronic Pain Medical Treatment Guidelines, opioids (criteria for use & specific drug list): A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. Guidelines recommend ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. The 4 A's for Ongoing Monitoring include analgesia, activities of daily living, adverse side effects, and aberrant drug- taking behaviors. Opioids may be continued if the patient has returned to work and the patient has improved function/pain. The ODG-TWC pain section comments specifically on criteria for the use of drug screening for ongoing opioid treatment. The ODG Pain/Opioids for chronic pain states "According to a major NIH systematic review, there is insufficient evidence to support the effectiveness of long-term opioid therapy for improving chronic pain, but emerging data support a dose-dependent risk for serious harms." ODG criteria (Pain / Opioids criteria for use) for continuing use of opioids include: (a) If the patient has returned to work; (b) If the patient has improved functioning and pain. Based upon the records reviewed there is insufficient evidence to support the medical necessity of chronic narcotic use. There is lack of demonstrated functional improvement, percentage of relief, return to work, or increase in activity from the exam note of 9/23/15. Therefore the prescription is not medically necessary and the determination is for non- certification.

Belsomra 10mg #30: 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) Mental Illness & Stress / Suvorexant (Belsomra).

Decision rationale: CA MTUS/ACOEM is silent on the issue of suvorexant. Per ODG Mental Illness & Stress/Suvorexant (Belsomra), the use of suvorexant is not recommended as a first-line treatment due to adverse effects. FDA approved a first-in-class insomnia drug suvorexant (Belsomra, ████████) 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 orexin, 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) In this case there is no evidence in the records from 9/23/15 of insomnia to warrant suvorexant. There is also no documentation of failure of a first-line agent. Therefore the request is not medically necessary.