

Case Number:	CM15-0184394		
Date Assigned:	09/24/2015	Date of Injury:	09/30/1998
Decision Date:	11/06/2015	UR Denial Date:	09/04/2015
Priority:	Standard	Application Received:	09/18/2015

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

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 66 year old male, who sustained an industrial injury on 09-30-1998. The injured worker is currently retired. Medical records indicated that the injured worker is undergoing treatment for chronic low back pain with bilateral leg pain, mixed level degenerative disc disease, facet disease-spondylosis, myofascial pain-spasm, hypertension, poor sleep hygiene, and severe coronary artery disease. Treatment and diagnostics to date has included lumbar spine MRI, use of medications, and urine drug screen dated 01-13-2015 was inconsistent with prescribed medications, but physician noted this was due to not having medications (per 08-25-2015 progress note). Current medications include Norco, Belsomra, and Nucynta ER. In progress notes dated 04-21-2015 and 08-25-2015, the injured worker reported chronic low back pain and bilateral foot pain with an average pain level of 9 out of 10 and noted poor sleep quality due to pain. Objective findings included ongoing low back pain with radicular pain into his leg with numbness and tingling to bilateral feet. The Utilization Review with a decision date of 09-03-2015 non-certified the request for Zohydro ER 20mg #60 and Belsomra 15mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Zohydro ER 20 mg #60: 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).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Medications for chronic pain, Opioids, criteria for use, Opioids for chronic pain.

Decision rationale: The patient presents with chronic low back and feet pain. The request is for Zohydro ER 20 MG #60. The request for authorization is not provided. MRI of the lumbar spine, 02/11/09, shows multilevel degenerative disc disease and spondylosis L1-S1. Physical examination reveals ongoing pain in low back with radicular pain into his legs, L>R. He has pain with lying down and standing as well. He complains of pain in bilateral soles of his feet with tingling and numbness of bilateral feet noted L>R. Per progress report dated 08/25/15, the patient is retired. MTUS, Criteria for Use of Opioids Section, pages 88 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS, Criteria For Use Of Opioids Section, page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS, Criteria for Use of Opioids Section, p77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, Medications for Chronic Pain Section, page 60 states that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." MTUS, p90 states, "Hydrocodone has a recommended maximum dose of 60mg/24hrs." MTUS, Opioids for Chronic Pain Section, pages 80 and 81 states "There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant radiculopathy," and for chronic back pain, it "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Treater does not specifically discuss this medication. This is the initial trial prescription for Zohydro. MTUS requires appropriate discussion of the 4A's, however, in addressing the 4A's, treater does not discuss how Norco significantly improves patient's activities of daily living with specific examples of ADL's. Analgesia is not discussed, specifically showing pain reduction with use of Norco. No validated instrument is used to show functional improvement. There is no documentation regarding adverse effects and aberrant drug behavior. UDT 01/13/15 is provided for review. In this case, long-term use of opiates may be indicated for nociceptive pain as it is "Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)." However, this patient does not present with pain that is "presumed to be maintained by continual injury." Therefore, the request IS NOT medically necessary.

Belsomra 15 mg #30: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental & Stress Chapter, under Suvorexant (Belsomra).

Decision rationale: The patient presents with chronic low back and feet pain. The request is for Belsomra 15 MG #30. The request for authorization is not provided. MRI of the lumbar spine, 02/11/09, shows multilevel degenerative disc disease and spondylosis L1-S1. Physical examination reveals ongoing pain in low back with radicular pain into his legs, L>R. He has pain with lying down and standing as well. He complains of pain in bilateral soles of his feet with tingling and numbness of bilateral feet noted L>R. Per progress report dated 08/25/15, the patient is retired. ODG Guidelines, Mental & Stress Chapter, 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) Per progress report dated 08/25/15, treater's reason for the request is "Sample trial of Belsomra worked well. He averaged 3-4 hours of uninterrupted sleep on Belsomra then he would wake up and go back to sleep." Patient has been prescribed Belsomra since at least 04/21/15. In this case, patient continues with low back pain and is diagnosed with poor sleep hygiene. Review of provided medical records shows medications tried/failed includes Ambien and Lunesta. The request for Belsomra appears reasonable and within ODG guideline indications. Therefore, the request IS medically necessary.