

Case Number:	CM14-0083465		
Date Assigned:	07/21/2014	Date of Injury:	08/16/2003
Decision Date:	08/26/2014	UR Denial Date:	05/28/2014
Priority:	Standard	Application Received:	06/04/2014

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. The expert reviewer is Board Certified in Occupational Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 patient is a 49 year old male maintenance utility worker who sustained injury on 8/16/2003 while he was cleaning and inspecting a bin. He leaned over to remove debris and pulled muscles in his low back. Treatment history includes medications, home exercise program and functional restoration program. The patient underwent L4-5 and L5-S1 hemilaminectomy and microdiscectomy on 1/04/2007 and revision in 8/2007. He also underwent spinal fusion on 06/23/2009 and 6/24/2009. Medication history includes Docusate Sodium 100mg Capsule, Promethazine 25 mg Tablets, Pantoprazole-Protonix 20mg, Cyclobenzaprine-Flexeril 7.5mg, Buprenorphine HCL Sublingual 2mg, Gabapentin Tablets 600mg, Gralise 600mg, Valium 10mg, Ibuprofen 300mg, Atripla tablet 600-200-300mg, and Rozerem 8 mg Tablet. Urine Analyte Interpretation dated 12/19/2013 showed positive results for Buprenorphine, Benzodiazepine, and Oxycodone. Visit note dated May 28, 2014 indicates that patient has had chronic pain since his back surgery and he feels that without the medication he would not be able to stand walk and do activities. On examination his motor muscle testing revealed 5/5 strength in bilateral lower extremities. The lumbar spine exam revealed a well healed surgical scar. Sensation is intact to light touch and pinprick in bilateral lower extremities. Straight leg raise is positive on the left and right with spasm and guarding noted. The patient was diagnosed with post lumbar laminectomy syndrome. The patient recommended Buprenorphine HCL 2mg #30 and Rozerem 8 mg # 30 with 5 refills. Prior UR dated May 28, 2014 denied the request for Buprenorphine HCL 2mg #30 and Rozerem 8 mg # 30 with 5 refills as medical necessity has not been established.

IMR ISSUES, DECISIONS AND RATIONALES

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

Buprenorphine HCL 2 mg # 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 26-27.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Buprenorphine Page(s): 26-27. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Buprenorphine for Opioid Dependence, for Chronic Pain.

Decision rationale: According to MTUS guidelines, Buprenorphine is recommended for treatment of opiate addiction. Buprenorphine is recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction. According to the Official Disability Guidelines, Buprenorphine is recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). Suggested populations: (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. In this case the patient is a 49-year-old male with chronic low back pain status post L3-S1 fusion in June of 2009. Records indicate the patient has improved ADL's and pain due to pain medication use. However, no objective measures are provided. The patient continues to complain of severe pain and dysfunction. Dependency on medical care has not decreased. The patient is not working. The opioid dose greatly exceeds the guideline recommended maximum of 120 morphine equivalent dosage. Medical necessity is not established.

Rozerem 8 mg # 30 with 5 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), Chronic Pain, 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), Pain, Insomnia Treatment.

Decision rationale: The California MTUS guidelines do not discuss the issue in dispute. According to Official Disability Guidelines, the majority of studies have only evaluated short-term treatment (i.e., 4 weeks) of insomnia; therefore more studies are necessary to evaluate the efficacy and safety of treatments for long-term treatment of insomnia. In 2007, the FDA requested that manufacturers of all sedative-hypnotic drugs strengthen product labeling regarding risks (i.e., severe allergic reactions and complex sleep-related behaviors, such as sleep driving). It is recommended that treatments for insomnia should reduce time to sleep onset, improve sleep maintenance, avoid residual effects and increase next-day functioning. Ramelteon (Rozerem) is a selective melatonin agonist (MT1 and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential). One systematic review concluded

that there is evidence to support the short-term and long-term use of Ramelteon to decrease sleep latency; however, total sleep time has not been improved. In this case, the patient is taking Rozerem for sleep latency with good affect. Other sleep medications have failed. There is believed to be no abuse potential for Rozerem. The request for #30 with 5 refills is not consistent with short-term or prn use. Therefore, this request is not medically necessary.