

Case Number:	CM15-0036579		
Date Assigned:	03/05/2015	Date of Injury:	05/10/2000
Decision Date:	04/20/2015	UR Denial Date:	01/26/2015
Priority:	Standard	Application Received:	02/26/2015

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 65-year-old male, who sustained an industrial injury on 5/10/2000. The diagnoses have included lumbar disc displacement. Treatment to date has included surgical and conservative measures. Currently, the injured worker complains of severe back pain, with radiation down his left leg. Pain was rated 9/10, at best 4/10 with medications, and 10/10 without. He remained off work. Exam of his back noted limited range of motion, bilateral straight leg raise tests were positive at 80 degrees, sensory loss in the left lateral calf and bottom of his foot, 4/5 weakness in left thigh flexion and great toe extension, and absent left Achilles reflex. Magnetic resonance imaging of the lumbar spine (5/06/2014) noted disc extrusion at L5-S1, impinging the left S1 nerve root, and stable post-surgical changes at L4-5. Medications included MS Contin 60mg (three times daily), Oxycodone IR 30mg (1 tablet every 4-6 hours as needed for breakthrough pain), Mobic 15mg daily, Quinine sulfate 325mg (at night for leg cramps), and Flexaril 10mg (every 6 hours as needed for spasms). On 1/26/2015, Utilization Review non-certified a request for Quinine Sulfate 325mg #30, and modified a request for Oxycodone IR 30mg #140 to Oxycodone IR 30mg #80, citing the MTUS Chronic Pain Medical Treatment Guidelines and Non-MTUS Guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

(1) Prescription of Oxycodone IR 30mg #140: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS Page(s): 76-78, 88-89.

Decision rationale: The patient presents with low back pain with shooting pain down the left leg. The Request for Authorization is dated 01/16/15. The current request is for 1 PRESCRIPTION OF OXYCODONE IR 30MG #140. For chronic opiate use, the MTUS guidelines pages 88 and 89 states, Pain should be assessed at each visit and function should be measured at 6-month intervals using a numerical scale or validated instrument. The MTUS page 78 also requires documentation of the 4 A's, which includes analgesia, ADLs, adverse side effects, and aberrant behavior. MTUS also requires 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. This patient has been prescribed this medication since at least 9/17/14. The treating physician states that the patient has 50% reduction in pain and 50% functional improvement with ADLs with medications versus not taking them. A narcotic contract is on file and UDS have been appropriate. In this case, recommendation for further use cannot be supported as the treating physician has not provided any specific functional improvement, changes in ADLs or change in work status to document significant functional improvement with utilizing long-term opiate. Furthermore, there are no discussions regarding adverse side effects as required by MTUS for opiate management. The treating physician has failed to provide the minimum requirements as required by MTUS for opiate management. This request IS NOT medically necessary and recommendation is for slow weaning per MTUS.

(1) Prescription of Quinine sulfate 325mg #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 FDA has the following, Qalaaquin (quinine sulfate) FDA.com.

Decision rationale: The patient presents with low back pain with shooting pain down the left leg. The Request for Authorization is dated 01/16/15. The current request is for 1 PRESCRIPTION OF QUININE SULFATE 325MG #30. The ACOEM, MTUS and ODG guidelines do not discuss Quinine Sulfate. The FDA has the following, Qalaaquin (quinine sulfate): New Risk Evaluation and Mitigation Strategy - Risk of serious hematological reactions. ISSUE: Due to continued reports of serious side effects in patients using Qalaaquin "off-label" for nighttime leg cramps, FDA has approved a risk management plan to warn against the use of this drug for such unapproved uses. Qalaaquin should not be used for nighttime leg cramps. Qalaaquin use may result in serious and life-threatening hematological reactions, including

serious bleeding due to thrombocytopenia, and hemolytic-uremic syndrome/ thrombotic thrombocytopenic purpura, which in some cases may result in permanent kidney damage. In some patients, adverse reactions result in hospitalization and death. BACKGROUND: Qualaquin is only FDA-approved for the treatment of uncomplicated malaria caused by the parasite Plasmodium falciparum, primarily in travelers returning from malaria-endemic areas. However, the majority of Qualaquin's use in the United States is for the treatment or prevention of nighttime leg cramps. The product labeling states that the risks associated with the use of Qualaquin in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps outweigh any potential benefits. The treating physician is prescribing this medication for neurogenic claudication leg cramps. The FDA warns against the use of Qualaquin for nighttime leg cramps and states Qualaquin use may result in serious and life-threatening hematological reactions. In this case, the FDA clearly states that Qualaquin should not be used for nighttime leg cramps. Given the lack of support for the use of this medication for leg cramps, recommendation cannot be made. This request IS NOT medically necessary.