

<b>Case Number:</b>	CM14-0166807		
<b>Date Assigned:</b>	10/14/2014	<b>Date of Injury:</b>	10/10/2005
<b>Decision Date:</b>	11/14/2014	<b>UR Denial Date:</b>	09/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/09/2014

### 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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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 injured worker is a 64 year-old male with a date of injury of 10/10/2005. The patient's industrially related diagnoses include lumbar discogenic syndrome, post-operative chronic pain, right thigh pain, and right ankle pain. The patient been taking tramadol 50mg one tab three times daily as needed with a 40% reduction of pain. Tramadol helps the patient with activities of daily living, and keeping his pain under control. No side effects were reported. The patient is also using lumbar brace and TENS unit with improvement of pain and function. The disputed issue is for refill of Tramadol / acetaminophen 37.5mg-325mg 90 tablets. A utilization review determination on 9/24/2014 has modified this request to 60 tablets. The stated rationale for the modification was stated as below. According to the utilization review, despite having a 40% symptomatic relief from medication, there is no documentation of objective functional gain with the use of this medication. In addition, there is no documentation of current urine drug test, risk assessment profile, attempt at weaning / tapering, and an updated and signed pain contract. A partial certification of tramadol / acetaminophen 37.5/325mg #60 was provided to allow opportunity for submission of documentation regarding compliance to Chronic Pain Medical Treatment Guidelines including urine drug testing, risk assessment profile, attempt at weaning/tapering, an updated signed pain contract, and evidence of objective functional benefit as a result of medication.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tramadol HCL/APAP 37.5/325mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Criteria Section, Tramadol Medication section Page(s): 94, 76-80.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on page 94 states the following regarding tramadol: "Tramadol is a synthetic opioid affecting the central nervous system. Tramadol is not classified as a controlled substance by the DEA. Side Effects: Dizziness, nausea, constipation, headache, somnolence, flushing, pruritus, vomiting, insomnia, dry mouth, and diarrhea. Tramadol may increase the risk of seizure especially in patients taking SSRIs, TCAs and other opioids. Do not prescribe to patients that at risk for suicide or addiction. Warning: Tramadol may produce life-threatening serotonin syndrome, in particular when used concomitantly with SSRIs, SNRIs, TCAs, and MAOIs, and triptans or other drugs that may impair serotonin metabolism. Analgesic dose: Tramadol is indicated for moderate to severe pain. The immediate release formulation is recommended at a dose of 50 to 100mg PO every 4 to 6 hours (not to exceed 400mg/day). This dose is recommended after titrating patients up from 100mg/day, with dosing being increased every 3 days as tolerated. For patients in need of immediate pain relief, which outweighs the risk of non-tolerability the initial starting dose, may be 50mg to 100mg every 4 to 6 hours (max 400mg/day). Ultram ER: Patient currently not on immediate release tramadol should be started at a dose of 100mg once daily. The dose should be titrated upwards by 100mg increments if needed (Max dose 300mg/day). Patients currently on immediate release tramadol calculate the 24-hour dose of IR and initiate a total daily dose of ER rounded to the next lowest 100mg increment (Max dose 300mg/day). (Product information, Ortho-McNeil 2003) (Lexi-Comp, 2008)" Since tramadol is an opioid, it is subject to the ongoing monitoring requirements as stated in the Chronic Pain Medical Treatment Guidelines, which specify on pages 78-79 the following: "On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function.(c) Office: 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of

opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse." According to the provided documents, the injured worker has been taking Tramadol since March 2014. A progress note from 7/9/2014 documents "good response to Tramadol." Another progress note from date of service May 9, 2014 had documented that the patient had 40% reduction in pain due to tramadol and improvement in activities of daily living. This is evidence of functional improvement. However, there is no monitoring of aberrant pain seeking behaviors such as urine drug screening or querying the state narcotic database (CURES). Without this monitoring, this request is not medically necessary.