

<b>Case Number:</b>	CM14-0096755		
<b>Date Assigned:</b>	07/28/2014	<b>Date of Injury:</b>	03/11/2011
<b>Decision Date:</b>	12/19/2014	<b>UR Denial Date:</b>	06/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/24/2014

### 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 Anesthesiology, has a subspecialty in Pain Management, and is licensed to practice in Georgia. 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:

This 59 year old male sustained industrial related continuous trauma injury from 04/01/1979 to 03/11/2011. The results of the injury included hypertension, diabetes, and a low back injury sustained on 03/11/2014. The injured worker was previously diagnosed with hypertension and diabetes. There were no current diagnoses listed on the PR2 dated 04/22/2014 or PR2 dated 05/20/2014. A PR2 dated 07/22/2014 showed diagnoses of lumbago and joint derangement NOS-shoulder. According to the request for authorization, dated 05/30/2014, orphenadrine citrate was requested for the treatment of muscle spasms and inability to sleep; Ondansetron ODT was requested for the treatment of nausea due to headaches and chronic pain; Tramadol was requested for the treatment of acute severe pain, and terocin patches were requested for the treatment of mild to moderate acute or chronic aches or pain. Progress reports dated from 04/22/2014 to 05/20/2014 revealed limited information and were illegible; however, a PR2 dated 07/22/2014 revealed the injured worker to have complaints of constant moderate low back pain that is aggravated with movement and prolonged sitting, standing or walking and described as sharp with radiation to the lower extremities. Moderate to severe pain to the bilateral shoulders is aggravated by activity and movement and described as throbbing. Treatment to date has included medications for hypertension and diabetes. There were no diagnostic studies or findings submitted. There was no documentation of current treatments for the low back and shoulder pain or headaches. There was no documentation of changes in pain level, functional deficits, or activities of daily living. Work functions were unchanged as the injured worker remained on modified work restrictions. Dependency on medical care appeared to be unchanged. The submitted application for Independent Medical Review (IMR) requested an appeal for the non-certification of Ondansetron ODT 8 mg x2 quantity #60, modification of orphenadrine citrate ER 100 mg #120, modification of Tramadol ER 150 mg #90, and non-certification of Terocin patch

#30. On 06/11/2014, Utilization Review non-certified prescriptions for ondansetron ODT and Terocin patches, and modified prescriptions for orphenadrine citrate and Tramadol which were requested on 06/03/2014. According to the UR, the requested Ondansetron ODT 8 mg x 2 quantities #60 was denied due to the non-recommendation of use for the treatment of opioid nausea and vomiting which was based on the ODG-TWC Pain Procedure Summary and the FDA-approved indications. This UR decision was appealed for an Independent Medical Review. The orphenadrine citrate ER 100 mg #120 was modified to orphenadrine citrate ER 100 mg #20 noting that muscle relaxants are not recommended for long term use. It was also noted that this medication is not listed as an "N" drug on the ODG-TWC Drug Formulary and that there was no documentation of failed trials of "Y" drugs in this category or any indication that the "N" drug is more beneficial than the "Y" drugs in this class. The risk of withdrawal symptoms from abrupt discontinuation was also noted. This UR decision was appealed for an Independent Medical Review. The Tramadol ER 150 mg #90 was modified to Tramadol ER 150 mg #60 noting the insufficient documentation of the severity of the injured worker's level of pain and/or efficacy with prior use. It was also noted that there was no documentation of current urine drug test, risk assessment profile, attempt at weaning or tapering the drug, and no signed pain contract between provider and injured worker. The MTUS Chronic Pain guidelines were cited for this decision. This UR decision was appealed for an Independent Medical Review. The Terocin patch #30 was denied due to the insufficient evidence of failed trials of anti-depressants and anti-convulsant therapy, and intolerance or insufficient response to other treatments prior to the use of Capsaicin. The MTUS Chronic Pain guidelines were cited for this decision. This UR decision was appealed for an Independent Medical Review.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Ondansetron 8mg, #30, x 2, quantity #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)-Treatment of Workers Compensation (TWC): Pain; Opioid nausea.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Emetics Page(s): 10. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Physician Desk Reference

**Decision rationale:** Ondansetron ODT 8 mg #30 x 2 quantity #60 is not medically necessary. The CA MTUS Guidelines indicates that antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Additionally, continuous long-term treatment by an anti-emetic is not recommended. The medical records does not document length of time the claimant has been on Ondansetron. With long term use in this case, the requested medication is not medically necessary.

**Orphenadrine Citrate ER 100mg, #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) - Treatment of Workers Compensation (TWC): Drug Formulary.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-spasmodics Page(s): 64.

**Decision rationale:** Orphenadrine Citrate ER 100mg #120 is not medically necessary. Ca MTUS "recommended non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain." Orphenadrine is an anticholinergic drug that is very sedating and is not recommended to combine with other sedating medications. The claimant is on Tramadol which is also a sedating medication; therefore the requested medication is not medically necessary.

**Tramadol ER 150mg, #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 64.

**Decision rationale:** Tramadol is a centrally- acting opioid. Per MTUS page 83, opioids for osteoarthritis are recommended for short-term use after failure of first line non-pharmacologic and medication option including Acetaminophen and NSAIDS. Additionally, Page 79 of MTUS guidelines states that weaning of opioids are recommended if (a) there are no overall improvement in function, unless there are extenuating circumstances (b) continuing pain with evidence of intolerable adverse effects (c) decrease in functioning (d) resolution of pain (e) if serious non-adherence is occurring (f) the patient requests discontinuing. The claimant's medical records did not document that there was an overall improvement in function or a return to work with previous opioid therapy. In fact, the claimant continued to report pain. The claimant has long-term use with this medication and there was a lack of improved function or return to work with this opioid and all other medications. Tramadol ER 150 #90 is not medically necessary. .

**Terocin patch #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** Terocin Patch #30 is not medically necessary. According to California MTUS, 2009, chronic pain, page 111 California MTUS guidelines does not cover "topical analgesics that are largely experimental in use with a few randomized controlled trials to determine efficacy or safety. Any compounded product that contains at least one drug or drug

class that is not recommended is not recommended". Additionally, Per CA MTUS page 111 states that topical analgesics are "recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (anti-depressants or AED). Only FDA-approved products are currently recommended. Non-neuropathic pain: Not recommended. The claimant was not diagnosed with neuropathic pain and there is no documentation of physical findings or diagnostic imaging confirming the diagnosis; therefore, the compounded mixture is not medically necessary.