

<b>Case Number:</b>	CM15-0210720		
<b>Date Assigned:</b>	10/29/2015	<b>Date of Injury:</b>	06/25/2003
<b>Decision Date:</b>	12/16/2015	<b>UR Denial Date:</b>	10/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/27/2015

### 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, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 female who sustained an industrial injury on 06-25-2003. According to a progress report dated 08-31-2015, the injured worker reported pain in her back that radiated down her legs bilaterally. Medications helped improve her function and included Methadone and Norco. With medications, pain was reduced from 9 to 10 on a scale of 1-10 to a 5 or 6. There had been no side effects or aberrant drug behavior. Sensation was decreased in L3, L4, L5 and right S1 dermatomes. Spasm and guarding of the lumbar spine was noted. The right hip was tender with motion. The right hip had capsular tightness. There was decreased range of motion with internal rotation and external rotation of the right hip. Current medications included Hydrocodone-APAP 10-325 mg every 8 hours, Pantoprazole 20 mg twice daily for stomach, Methadone 5 mg 3 tablets in the morning, 2 tablets at noon and 3 tablets at night, Amlodipine, Lisinopril and Synthroid. Diagnoses included long term use meds not elsewhere classified, lumbago, degeneration lumbar lumbosacral disc, pain in joint pelvis thigh and depression with anxiety. Prescriptions were provided for Hydrocodone-APAP 10-325 mg #90, Pantoprazole 20 mg quantity 60 and Methadone HCL 5 mg #240. Work status was noted as permanent and stationary. Follow up was indicated in 4 weeks. Documentation submitted for review shows long term use of Methadone and Pantoprazole. On 10-22-2015, Utilization Review non-certified the request for Methadone HCL 5 mg Quantity 240 (retrospective date of service 08-31-2015) and Pantoprazole-Protonix 20 mg quantity 60 (retrospective date of service 08-31-2015).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Methadone HCL 5 mg Qty 240 (retrospective DOS 08/31/2015): Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification), Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids, criteria for use, Opioids for chronic pain, Opioids for neuropathic pain, Opioids for osteoarthritis, Opioids, cancer pain vs. nonmalignant pain, Opioids, dealing with misuse & addiction, Opioids, differentiation: dependence & addiction, Opioids, dosing, Opioids, pain treatment agreement.

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

**Decision rationale:** With regard to methadone, the MTUS CPMTG states: "Recommended as a second-line drug for moderate to severe pain if the potential benefit outweighs the risk. The FDA reports that they have received reports of severe morbidity and mortality with this medication. This appears, in part, secondary to the long half-life of the drug (8-59 hours). Pain relief on the other hand only lasts from 4-8 hours. Methadone should only be prescribed by providers experienced in using it." Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of opioids "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 nonadherent) drug related behaviors. These domains have been summarized as the "4 A's" (Analgesia, activities of daily living, adverse side effects, and any 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." It was noted per progress report dated 8/21/15 that the injured worker rated pain 8/10 without medications and 4/10 with medications. She reported that medications help her to better tolerate her activities of daily living including walking and standing, and she is able to perform her home exercise program with less pain. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 7/2/15 was positive for methadone metabolite. It is noted that the injured worker's morphine equivalent dose is 150mg MED, which exceeds the guideline recommended 120 mg MED. However, per the guidelines, the daily dose of opioid may be increased above 120 mg MED after pain management consultation. As the provider is a pain management specialist, and the medication allows the injured worker to maintain functional ability, the request is medically necessary.

**Pantoprazole-Protonix 20 mg Qty 60 (retrospective DOS 08/31/2015): Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Proton pump inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Proton Pump Inhibitors.

**Decision rationale:** In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). CPMTG guidelines further specify: "Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)" Per ODG TWC, "many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line." Per the medical records, it was noted that the injured worker had utilized NSAIDs such as Meloxicam in the past and had a history of some gastric side effects with the use of these medications. It was noted that she had tried omeprazole in the past and did not find it to be beneficial with her GI symptoms. It was noted that she is currently able to manage her GI disturbances with the use of Protonix. I respectfully disagree with the UR physician's assertion that there was no documentation of gastrointestinal disturbance. The request is medically necessary.