

<b>Case Number:</b>	CM15-0166059		
<b>Date Assigned:</b>	09/03/2015	<b>Date of Injury:</b>	07/10/2009
<b>Decision Date:</b>	10/22/2015	<b>UR Denial Date:</b>	08/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/24/2015

### 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: Arizona, Michigan  
 Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 48 year old female who sustained an industrial injury to her lower back on 07-10-2009. The injured worker was diagnosed with lumbago. No surgical interventions were documented. Treatment to date has included diagnostic testing, physical therapy, acupuncture therapy, Toradol intramuscularly, steroids intramuscularly and oral medications. According to the primary treating physician's progress report on June 25, 2015, the injured worker continues to experience low back pain. Examination demonstrated tenderness to palpation of the paravertebral muscles with spasm. Seated nerve root test is positive. Range of motion was guarded and restricted. No evidence of instability was documented. Gait, coordination and neurovascular status were intact. An intramuscular injection of DepoMedrol and Marcaine along with vitamin B-12 complex was administered at the office visit. Current medications were listed as Tylenol #4, Nabumetone, Cyclobenzaprine, Nabumetone, Ondansetron and Prevacid. Treatment plan consists of continuing with medication regimen, lumbar spine magnetic resonance imaging (MRI), Electromyography (EMG), Nerve Conduction Velocity (NCV) of the bilateral upper extremities and the current request for Acetaminophen/Codeine (Tylenol #4) 300-60mg, Cyclobenzaprine, Nabumetone and Lansoprazole (Prevacid) Delayed Releasing Capsule and Ondansetron.

### IMR ISSUES, DECISIONS AND RATIONALES

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

### **Ondansetron 8mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Antiemetics (for opioid nausea).

**Decision rationale:** The MTUS/ACOEM did not specifically address the use of ondansetron in the injured worker therefore other guidelines were consulted. Per the ODG ondansetron is not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) Ondansetron (Zofran): This drug is a serotonin 5-HT<sub>3</sub> receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. A review of the injured workers medical records that are available to me reveal that it appears that the injured worker is being prescribed ondansetron for opioid induced nausea, the guidelines do not support the use of ondansetron for this purpose, therefore the request for Ondansetron 8mg #30 is not medically necessary.

### **Acetaminophen/Codeine (Tylenol #4) 300-60mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of

opioids should be regularly reassessed. In the maintenance phase, the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. It is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. A review of the injured workers medical records that are available to me do not reveal documentation of improvement in pain or function with the use of this medication according to guideline recommendations, without this information it is not possible to establish medical necessity. Therefore, the request for Acetaminophen/Codeine (Tylenol #4) 300-60mg #60 is not medically necessary.

**Nabumetone (Relafen) 650mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** Per the MTUS, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. A review of the injured workers medical records that are available for my review did not reveal any documentation of improvement in pain or function with the use of this medication, without this information, medical necessity is not established, therefore the request for Nabumetone (Relafen) 650mg #120 is not medically necessary.

**Lansoprazole (Prevacid) Delayed Releasing Capsule 30mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**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 (Chronic)/Proton Pump Inhibitors (PPIs).

**Decision rationale:** Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 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). Per the ODG, PPI's are "Recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)" A review of the injured workers medical records that are available to me did not reveal that the injured worker is at increased risk for a gastrointestinal event according to guideline criteria, therefore the request for Lansoprazole (Prevacid) Delayed Releasing Capsule 30mg #120 is not medically necessary.

**Cyclobenzaprine Hydrochloride 7.5mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril).

**Decision rationale:** Per the MTUS, Cyclobenzaprine is recommended as an option in the treatment of chronic pain using a short course of therapy. It is more effective than placebo in the management of back pain, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment suggesting that shorter courses may be better. Treatment should be brief. Treatment is not recommended for longer than 2-3 weeks. A review of the injured workers medical records that are available for my review did not reveal any documentation of improvement in pain or function with the use of this medication, without this information medical necessity is not established, therefore the request for Cyclobenzaprine is not medically necessary.