

<b>Case Number:</b>	CM15-0129968		
<b>Date Assigned:</b>	07/16/2015	<b>Date of Injury:</b>	01/01/2000
<b>Decision Date:</b>	09/09/2015	<b>UR Denial Date:</b>	06/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/06/2015

### 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: New York

Certification(s)/Specialty: Internal 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 54 year old female, who sustained an industrial injury on 1/1/2000. The mechanism of injury is unclear. The injured worker was diagnosed as having reflex sympathetic dystrophy syndrome of upper limb, lumbar disc displacement, myalgia and myositis, and depressive disorder. Treatment to date has included medications, ganglion block, and home exercise program, magnetic resonance imaging of the lumbar spine, physical therapy, and psychological evaluation. The request is for Pantoprazole, Diclofenac Potassium, and Buprenorphine 2mg-Naloxone 0.5mg sublingual. On 3/5/2015, she rated her right upper extremity and right shoulder pain as 7/10 and indicated it was similar to her previous appointment. The treatment plan included: Buprenorphine, diclofenac potassium, Gabapentin, Lexapro, and Mirtazapine. On 6/2/2015, she complained of hand pain, right upper extremity pain, and is also being seen for low back pain. She rated her right upper extremity and right shoulder pain 7/10 and indicated it was similar to her previous visit. She reported that with some medications and a home exercise program she is independent in her activities of daily living, although she continues with poor mood and poor sleep. Physical examination revealed normal gait and posture; no muscle atrophy in the upper extremities, swelling is noted over the palm of the hand and wrist on the left. The records note she has been able to wean off of high dose opioid medications with the use of buprenorphine which allows her to perform a home exercise program and maintain independence. She is noted to have resigned an opioid contract in December 2014, and CURES showed no entries. The treatment plan included: Pantoprazole, diclofenac potassium and Buprenorphine. She is noted to take over the counter Tylenol for flares.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Pantoprazole 20mg #30, 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Proton pump inhibitors and Other Medical Treatment Guidelines Drugs.com.

**Decision rationale:** Per Drugs.com, Pantoprazole is a proton pump inhibitor. The CA MTUS does not specifically address Pantoprazole. However, the CA MTUS recommends co-therapy of non-steroidal anti-inflammatory agents (NSAIDs) with a proton pump inhibitor (PPI) in patients who are determined to be at intermediate or high risk of a gastrointestinal (GI) event. The ODG guidelines recommend proton pump inhibitors for patients at risk for gastrointestinal events. 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. 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). 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. In this case, the injured worker is noted to take Diclofenac potassium which is an NSAID; however the records do not indicate she was at risk or is currently at risk for gastrointestinal events. She has also been taking Pantoprazole on a long term basis without documented benefit. Therefore, the request for Pantoprazole is not medically necessary.

**Diclofenac Potassium 50mg #60 with 2 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs); Diclofenac Page(s): 43, 67-73.

**Decision rationale:** The CA MTUS indicates Diclofenac is a non-steroidal anti-inflammatory drug (NSAID). Per the MTUS, non-steroidal anti-inflammatory drugs (NSAIDs) are

recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The MTUS does not recommend chronic NSAIDs for low back pain; NSAIDs should be used for the short term only. Systemic toxicity is possible with NSAIDs. The [REDACTED] and MTUS recommend monitoring of blood tests and blood pressure. Package inserts for NSAIDs recommend periodic monitoring of a complete blood count (CBC) and chemistry profile (including liver and renal function tests). The records indicate she has utilized Diclofenac on a long-term basis. In addition, the records do not indicate monitoring of the blood pressure or blood work as recommended. Therefore, the request for Diclofenac Potassium 50mg #60 with 2 refills is not medically necessary.

**Buprenorphine 2mg- Naloxone 0.5mg sublingual #150 with 2 refills: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain; Opioids Page(s): 60-61, 74-95. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Buprenorphine; Pain chapter, Naloxone.

**Decision rationale:** Per the CA MTUS guidelines, Buprenorphine/Naloxone also known as Subutex or Suboxone is used to treat opiate agonist dependence. Buprenorphine is an analgesic, partial opioid agonists, and Naloxone is an opioid antagonist used to reverse the effects of agonists and agonist-antagonist derived opioids. There is no indication The ODG guidelines recommend Buprenorphine as an option for treatment of chronic pain in selected patients, and not as a first-line for all patients. The suggested patients would include: patients with a hyperalgesic component to pain, patients with centrally mediated pain, patients with neuropathic pain, patients at high risk of non-adherence with standard opioid maintenance, and for analgesia in patients who have previously been detoxified from other high dose opioids. The CA MTUS Chronic Pain Medical Treatment Guidelines indicates that management of opioid therapy should include 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. In this case, the records indicate she has been diagnosed with reflex sympathetic dystrophy syndrome of the upper extremity. The records indicate Buprenorphine-Naloxone was prescribed for pain, her pain level was rated 7/10, and was indicated to have remained unchanged. The records do not indicate her least reported pain over the period since her last assessment; her average pain with the use of Buprenorphine-Naloxone; the intensity of pain after taking Buprenorphine-Naloxone; how long it takes for pain relief to occur with

Buprenorphine-Naloxone; and how long pain relief lasts with the use of Buprenorphine-Naloxone. The records also do not indicate her current functional status as compared to her previous assessment while utilizing Buprenorphine-Naloxone, or indicate any known side effects with the use of Buprenorphine-Naloxone. Therefore, the request for Buprenorphine 2mg-Naloxone 0.5mg sublingual #150 with 2 refills is not medically necessary. Of note, discontinuation should include a taper to avoid withdrawal symptoms.