

<b>Case Number:</b>	CM15-0116115		
<b>Date Assigned:</b>	06/24/2015	<b>Date of Injury:</b>	11/29/1993
<b>Decision Date:</b>	08/28/2015	<b>UR Denial Date:</b>	06/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/16/2015

### 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: North Carolina

Certification(s)/Specialty: Family Practice

### 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 November 29, 1993. The initial diagnosis and symptoms experienced were not included in the documentation. Treatment to date has included heat-cold therapy, rest, medication, massage and home exercise program. Currently, the injured worker complains of neck, shoulder and lumbar pain described as dull, aching, throbbing, weakness and spasms. The pain is rated 3-8 on 10 and is aggravated by activity, standing and walking. The injured worker is diagnosed with lumbar radiculopathy, post cervical laminectomy syndrome, cervical radiculopathy, chronic shoulder pain, cervicalgia and rotator cuff disorder. Her work status is permanent and stationary. A note dated April 14, 2015 states the injured worker is stable with her medication. The note further states the injured worker experiences pain relief from heat-cold therapy, rest, medication and massage. The following, toxicology screen (to monitor medication compliance), Omeprazole DR 20 mg #30 (due to non-steroidal anti-inflammatory use) and Celebrex 200 mg #30 (for inflammation and assist to alleviate pain) are requested.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Toxicology screen:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Urine drug testings (UDT).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 76-84.

**Decision rationale:** The California chronic pain medical treatment guidelines section on opioids states: 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 diary 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. The California MTUS does recommend urine drug screens as part of the criteria for ongoing use of opioids .The patient was on opioids at the time of request and therefore the request is medically necessary.

**Omeprazole 20 mg CPDR (capsule delayed release) Qty 30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID Page(s): 68.

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID therapy and proton pump inhibitors (PPI) states: Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastro duodenal lesions. 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 mg 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. There is no documentation provided that places this patient at intermediate or high risk that would justify the use of a PPI. There is no mention of current gastrointestinal or cardiovascular disease. For these reasons, the criteria set forth above per the California MTUS for the use of this medication has not been met. Therefore, the request is not medically necessary.

**Celebrex 200 mg Qty 30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID Page(s): 68-72.

**Decision rationale:** The California chronic pain medical treatment guidelines section on NSAID use and proton pump inhibitors (PPI) states: Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. 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 mg 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. Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents.

(Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) Use with Aspirin for cardio-protective effect: In terms of GI protective effect: The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007) In terms of the actual cardio-protective effect of aspirin: Traditional NSAIDs (both ibuprofen and naproxen) appear to attenuate the antiplatelet effect of enteric-coated aspirin and should be taken 30 minutes after ASA or 8 hours before. (Antman, 2007) Cox-2 NSAIDs and diclofenac (a traditional NSAID) do not decrease anti-platelet effect. (Laine, 2007) Per the California MTUS guidelines, Cox-2 agents like Celebrex are indicated for patients at intermediate or high gastrointestinal risk. While the patient has had non-specific GI complaints, there are no documented risk factors that place the patient at intermediate or high risk as set forth above. Therefore, the medication does not meet criteria and is not medically necessary.