

<b>Case Number:</b>	CM15-0100153		
<b>Date Assigned:</b>	06/02/2015	<b>Date of Injury:</b>	01/09/1999
<b>Decision Date:</b>	07/08/2015	<b>UR Denial Date:</b>	05/13/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/26/2015

### 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 71 year old female, who sustained an industrial injury on 1/9/99. Initial complaints were not reviewed. The injured worker was diagnosed as having cervical strain; right shoulder strain; right lateral epicondylitis-lesser right medial epicondylitis; left lateral epicondylitis; bilateral hand/wrist repetitive strain injuries with bilateral numbness and tingling; bilateral upper extremity repetitive strain injury; chronic pain. Treatment to date has included medications. Currently, the PR-2 notes 1/7/15 dated were submitted for review. These notes indicated the injured worker has repeatedly noted that the brand name Prilosec has better formulation and effectiveness than the generic. The provider documents "Apparently, brand name Prilosec is on order for \$600 and it can be on the order of \$0.50 a pill. For a quantity 60, that would be \$30 a month, and this would be a matter for better service from their pharmacy vendor such as walking across an aisle and pulling the medication off a shelf or ordering it as an OTC. I will review this with the injured worker when she comes back in, but she has consistently done better with the generics. This includes some of the other medications that she is on as well." The provider offered no other medical documentation in support of the requested Celebrex 200mg #60 with one refill and Prilosec 20mg #90 with two refills.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Celebrex 200mg #60 with 1 refill: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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 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. 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 cardioprotective 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 cardioprotective 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.

**Prilosec 20mg #90 with 2 refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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 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 a 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 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. 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.