

Case Number:	CM15-0011156		
Date Assigned:	01/29/2015	Date of Injury:	03/03/2005
Decision Date:	03/18/2015	UR Denial Date:	12/23/2014
Priority:	Standard	Application Received:	01/21/2015

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: District of Columbia, Virginia
 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 72 year old male, who sustained an industrial injury on March 3, 2005. The diagnoses have included lumbosacral spondylosis, lumbar spinal stenosis, and lumbosacral sprain. Treatment to date has included an MRI in 2005, work modifications, urine drug screening, pain, muscle relaxant, non-steroidal anti-inflammatory, and proton pump inhibitor medications. On December 15, 2014, the treating physician noted improved pain and muscle spasms since last visit. The injured worker's medications are helpful. The injured worker has reflux from the medications, and this is decreased with the proton pump inhibitor medication. Currently, the injured worker is using pain, proton pump inhibitor, muscle relaxant, and non-steroidal anti-inflammatory medications. The physical exam revealed the bilateral upper and lower extremities had normal reflex, sensory, and power testing. Bilateral straight leg raise and bowstring were negative. The injured worker had a normal gait, and was able to heel/toe walk bilaterally. There was lumbar tenderness, about a 20% decrease in lumbosacral range of motion, bilateral femoral stretch was negative, and bilateral lower extremities pulses were normal. On December 23, 2014 Utilization Review non-certified a prescription for Protonix 20mg #60, noting there must be sufficient documentation of medical necessity consistent with the guidelines, and the lack of documentation of a first line proton pump inhibitor as Protonix is a second line proton pump inhibitor. The California Medical Treatment Utilization Schedule (MTUS), Chronic Pain Medical Treatment Guidelines and Official Disability Guidelines (ODG) were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Protonix 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines - Pain Chapter- Proton Pump Inhibitors (PPIs)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792 Page(s): 68-69.

Decision rationale: Per MTUS: NSAIDs, GI symptoms & cardiovascular risk: 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 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 µg 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 aPPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) 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)

Use of NSAIDs and SSRIs: The concurrent use of SSRIs and NSAIDs is associated with moderate excess relative risk of serious upper GI events when compared to NSAIDs alone. This risk was higher for non-selective NSAIDs when compared to Cox-2 selective agents (adjusted odds ratio of 1.77 and 1.33, respectively). (Helin-Salmivaara, 2007) Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI. This patient did have risk factors for GI bleed and was receiving an NSAID. However, based on the cited guidelines, lifelong GI prophylaxis would not be indicated.