

<b>Case Number:</b>	CM15-0178572		
<b>Date Assigned:</b>	09/18/2015	<b>Date of Injury:</b>	09/18/2014
<b>Decision Date:</b>	10/27/2015	<b>UR Denial Date:</b>	08/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/11/2015

### 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: California

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 25-year-old male who sustained an industrial injury on 9-18-14. He was treated for low back pain and underwent an anterior lumbar discectomy and inter-body stabilization at L5-S1. Progress report dated 7-23-15 reports continued complaints of lower back pain rated 6 out of 10 and leg pain that comes and goes. Objective findings: wound healed, tender lumbar spine, neurological checks within normal limits, calves soft. X-ray of lumbar spine shows good position of hardware L5-S1. Diagnoses include disc displacement, anomaly of spine, and lumbosacral neuritis or radiculitis. Plan of care includes: may begin physical therapy, medications provided at this visit see medication log, medications; flexeril 7.5 mg, protonix 20 mg one per day, norco 5-325 mg, and Ultram 50 mg Work status: remain off work for 45 days.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Protonix 20mg #60 with 1 refill (DOS 07/27/2015): Upheld**

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

**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) Chapter Proton Pump Inhibitors (PPIs).

**Decision rationale:** Based on ODG guidelines, proton pump inhibitors like protonix are recommended 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. (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) Risks: Decisions to use PPIs long-term must be weighed against the risks. The potential adverse effects of long-term PPI use include B12 deficiency; iron deficiency; hypomagnesemia; increased susceptibility to pneumonia, enteric infections, and fractures; hypergastrinemia and cancer; and more recently adverse cardiovascular effects. PPIs have a negative effect on vascular function, increasing the risk for myocardial infarction (MI). Patients with gastroesophageal reflux disease on PPIs had a 1.16 greater risk of MI, and a 2.00 risk for cardiovascular mortality. PPI usage may be serving as a marker for a sicker population, but this is unlikely, given the lack of increased risk seen in patients taking H2 blockers. (Shah, 2015) In this study PPI use was associated with a 1.58-fold greater risk of MI, and in the case-crossover study, adjusted odds ratios of PPI for MI risk were 4.61 for the 7-day window and 3.47 for the 14-day window. However, the benefits of PPIs may greatly outweigh the risks of adverse cardiovascular effects, with number needed to harm of 4357. (Shih, 2014) Outpatient PPI use is associated with a 1.5-fold increased risk of community-acquired pneumonia, with the highest risk within the first 30 days after initiation of therapy. (Lambert, 2015) The updated Beers Criteria, which help prevent adverse drug events in older adults, added a recommendation to avoid the use of PPIs for more than 8 weeks, except for long-term NSAID users and patients with erosive esophagitis, Barrett's esophagitis, pathologic hypersecretory condition, or a demonstrated need for maintenance therapy. There are many studies demonstrating, in elderly patients, an increased risk for Clostridium difficile infection and bone loss and fractures with the long-term use of PPIs. 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). A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use. In this case, the patient appears to be low risk and

does not have a history of gastrointestinal disease, nor does he have gastrointestinal symptoms. Therefore, based on the ODG guidelines and the information in this case, the request for retrospective protonix 20 mg #60 with 1 refill is not medically necessary.