

<b>Case Number:</b>	CM15-0176823		
<b>Date Assigned:</b>	09/17/2015	<b>Date of Injury:</b>	02/07/2004
<b>Decision Date:</b>	10/27/2015	<b>UR Denial Date:</b>	08/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/08/2015

### 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, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This injured worker is a 57 year old male who reported an industrial injury on 2-7-2004. His diagnoses, and or impressions, were noted to include: cervical stenosis and spondylosis without myelopathy; carpal tunnel syndrome; lumbar disc disease and intractable and chronic pain, status-post intrathecal pain pump; gastrointestinal reflux disease (GERD) secondary to industrial injury; somatic symptom disorder with predominant pain; non-healing surgical wound; and major depression. No current imaging studies were noted. His treatments were noted to include: weekly individual cognitive-behavioral psychotherapy (approx. 10 sessions); implantation of a pain pump (6-2-15); Emergency Room visits for Fentanyl Patch and pump overdose (6-5-15), and mild purulent discharge from newly inserted pain pump to the lower abdominal quadrant (6-15-15); a motorized wheelchair; medication management with toxicology studies; and rest from work as he was noted to be disabled. The progress notes of 7-13-2015 reported complaints which included: > 10 years of constant, bilateral shoulder, elbow and wrist pain, rated 8 out of 10, and muscle spasms, along with swelling and loss of feeling in the bilateral lower extremities; pain that radiated to the back, bilateral upper and lower extremities, bilateral buttock and head; that he was in severe pain made worse by movement, weather, activity and activities of daily living, and made better by rest and medications; of feeling blue, frustrated and unrested due to pain, symptoms, and insomnia; and that he presented for a rate increase and medication refill. Objective findings were noted to include: no acute distress; obesity; an antalgic gait with use of cane and wheel chair; decreased bilateral grip strength; decreased sensation in the cervical dermatomes; positive impingement test in the bilateral shoulders; decreased strength in the upper

and lower extremities, severe in the bilateral wrists; no abnormal gastrointestinal or abdominal assessment findings; an intact dressing to the low and med-back that was without active bleeding or drainage; and that he requested a bolus before he left the clinic, in addition to his rate increase, and requested he would like 3 bolus in a day at 10:00, 16:00 and 21:00. His current medications were noted to include Protonix 40 mg tablet, delayed release, 1 tablet every morning for 30 days, dispense 30 tablets, refills 6. The physician's requests for treatments were noted to include a refill of Protonix 20 mg, 1 by mouth every morning for GERD secondary to industrial injury. The progress notes of 7-20-2015 note no significant changes in assessment findings, and state the pump site was clean and dry, without signs-symptoms of infection or seroma; and his current medications were noted to include Protonix 40 mg tablet, delayed release, 1 tablet every morning for 30 days, dispense 30 tablets, refills 6 with the request for Protonix 20 mg, 1 by mouth every morning for GERD secondary to industrial injury. Aside from the change in the abdominal assessment noting a slow healing area to lateral aspect of abdominal incision that was cleaned and left open to air; and the report of improvement in pain with the adjustment in his pain pump regimen, with the flex pattern changed to allow for 3 bolus's a day, and discontinuation of his Fentanyl Patches, no significant changes in the progress notes of 7-27-2015 were noted. A refill for Protonix 20 mg, 1 by mouth every morning for GERD secondary to industrial injury was noted. The Request for Authorization for Protonix was not noted in the medical records provided. The Utilization Review of 8-13-2015 non-certified 30 tablets of Protonix 20 mg.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Protonix 20 mg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain/Proton pump inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Proton Pump Inhibitors.

**Decision rationale:** In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (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). CPMTG guidelines further specify: "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. 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 a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)" Per ODG TWC, "many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line." As there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low, as such, medical necessity cannot be affirmed. Furthermore, as noted per the guidelines, Protonix is a second-line medication. The medical records do not establish whether the patient has failed attempts at first line PPIs, such as omeprazole or lansoprazole, which should be considered prior to prescribing a second line PPI such as Protonix. The request is not medically necessary.