

<b>Case Number:</b>	CM15-0205230		
<b>Date Assigned:</b>	10/22/2015	<b>Date of Injury:</b>	10/18/2012
<b>Decision Date:</b>	12/09/2015	<b>UR Denial Date:</b>	09/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/19/2015

### 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:

The injured worker is a 53 year old male, who sustained an industrial injury on 10-18-12. The documentation on 9-4-15 noted that the injured worker has complaints of lower back pain, left lower extremity pain and right lower extremity pain and headaches. The injured worker rates the pain as 4 out of 10 with 0 being no pain and 10 having the worst pain possible. The injured worker reports that his condition is associated with abnormal gait, difficulty in ambulation, muscle spasms and numbness tingling of affected limbs and is aggravated by carrying prolonged standing and prolonged walking. The injured worker states that medications are less effective. Lumbar spine examination revealed loss of normal lordosis with straightening of the lumbar spine and range of motion is restricted. On palpation, paravertebral muscles, tenderness and tight muscle band is noted on the right side. Spinous process tenderness is noted on L3, L4 and L5 and lumbar facet loading is positive on both sides. Straight leg raising test is positive on the right side and tenderness noted over the sacroiliac spine. Bilateral knee examination reveal that range of motion is restricted with flexion limited to 100 degrees limited by pain and extension limited to 160 degrees limited by pain. On sensory examination, light touch sensation is decreased over L4, L5, S1 (sacroiliac) dermatomes on the right side. Lumbar spine magnetic resonance imaging (MRI) on 4-15-15 revealed degenerative disc disease at L3-4 and L5-S1 (sacroiliac); 5 millimeter broad-based disc bulge at L5-S1 (sacroiliac); moderate right-sided neuroforaminal stenosis at this level and mild to moderate facet osteoarthritis at L4-5 and L5-S1 (sacroiliac). The diagnoses have included displacement of lumbar intervertebral disc without myelopathy. Treatment to date has included spinal injection with 3 months benefit; Functional

Restoration Program initial evaluation completed on 11-3-14; norco that reduced his pain in the back from 7 out of 10 to 4 out of 10 and is able to get up out of bed and perform activities of daily living and last about 3 to 3.5 hours; morphine for breakthrough pain; ambien has improved his sleep; advil and pantoprazole. The injured worker reports that norco and two advil make the headaches cease. The documentation noted that the injured worker has been on norco and pantoprazole since at least 3-6-15. The original utilization review (9-17-15) non-certified the request for pantoprazole sodium DR (delayed release) 20 mg quantity 60. The request for norco 10-325mg quantity 120 has been modified to norco 10-325mg #90.

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

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

#### **Pantoprazole Sodium DR (delayed release) 20 mg Qty 60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**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 indicate that the injured worker was previously treated with omeprazole between 3/2015 and 5/2015, with no indication that it was ineffective. The request is not medically necessary.

**Norco 10/325 mg Qty 120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding on-going management of Opioids, 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 any 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. Review of the available medical records reveals no documentation to support the medical necessity of norco nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends discontinuing opioids if there is no overall improvement in function, is not medically necessary.