

Case Number:	CM15-0219342		
Date Assigned:	11/12/2015	Date of Injury:	08/18/2010
Decision Date:	12/29/2015	UR Denial Date:	10/16/2015
Priority:	Standard	Application Received:	11/07/2015

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 38-year-old female who sustained an industrial injury on 08-18-2010. Medical records indicated the worker was treated for lumbar disc displacement without myelopathy. On 09-24-2015, she is seen for a medication refill. In the last visit note that detailed subjective complaints, she reports lower back pain made worse with bending and lifting. She has increased numbness and tingling in the right lower extremity and denies drowsiness with gabapentin use. She reports excellent analgesia from Norco and Zanaflex with pain decreases with the combination. She takes these only at night as they cause slight drowsiness. The worker is a graduate of a functional rehabilitation program and continues with home exercises. Her medications continue to provide ongoing pain relief, as well as functional improvement. Medications include Zanaflex (since at least 04-07-2015), Norco (since at least 04-07-2015), Pantoprazole (since at least 05-05-2015), and gabapentin (since at least 05-05-2015). Urine drug screens (last done 04-07-2015) reflect compliance with prescribed medications. A request for authorization was submitted for: 1. Pantoprazole-Protonix 20 mg Qty 30; 2. Hydrocodone/APAP 10/325 mg Qty 45; 3. Zanaflex 4 mg Qty 90; 4. Gabapentin 600 mg Qty 90. A utilization review decision 10-16-2015 denied: Pantoprazole-Protonix 20 mg Qty 30; Hydrocodone/APAP 10/325 mg Qty 45 Approved: Zanaflex 4 mg Qty 90; Gabapentin 600 mg Qty 90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Pantoprazole-Protonix 20 mg Qty 30: 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 mg 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 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.

Hydrocodone/APAP 10/325 mg Qty 45: Upheld

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

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 nonadherent) 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 neither documentation to support the medical necessity of Hydrocodone/APAP 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. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS dated 5/8/15 was consistent with prescribed medications. As MTUS recommends discontinuing opioids if there is no overall improvement in function, medical necessity cannot be affirmed.