

Case Number:	CM15-0240210		
Date Assigned:	12/17/2015	Date of Injury:	06/15/2011
Decision Date:	01/27/2016	UR Denial Date:	11/24/2015
Priority:	Standard	Application Received:	12/09/2015

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 is a year 59 old female with a date of injury on 6-15-11. A review of the medical records indicates that the injured worker is undergoing treatment for neck, lower back, right shoulder, and right knee pain. Progress report dated 11-12-15 reports continued complaints of neck pain that comes and goes with stiffness rated 6-7 out of 10. Right shoulder pain is better, on and off rated 5 out of 10. She is unable to sleep on the right shoulder. Lower back pain is frequent with shooting pain to the right greater than left legs rated 7 out of 10. She has complaints of right wrist popping with minimal pain. Objective findings: lumbar spine tender to palpation with spasms in the para-spinal muscles, and range of motion is decreased. Request for authorization was made for Tramadol ER 150 mg (unspecified quantity) and Protonix 20 mg (unspecified quantity). Utilization review dated 11-24-15 non-certified the request.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 150mg (unspecified quantity): Upheld

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

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 ongoing 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 reveal neither documentation to support the medical necessity of Tramadol 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. There is no documentation comprehensively addressing this concern in the records available for my review. Furthermore, the request does not specify quantity information. As MTUS recommends discontinuing opioids if there is no overall improvement in function, the request is not medically necessary.

Protonix 20mg (unspecified quantity): Upheld

Claims Administrator 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), 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 (200g 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 cardio protection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is Naproxen 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. Furthermore, the request does not specify quantity information. The request is not medically necessary.