

Case Number:	CM15-0188580		
Date Assigned:	09/30/2015	Date of Injury:	04/23/2015
Decision Date:	11/13/2015	UR Denial Date:	08/24/2015
Priority:	Standard	Application Received:	09/24/2015

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 52 year old male who sustained an industrial injury on 04-23-2015. Medical records indicated the worker was treated for contusion of the shoulder, thoracic, and lumbar spine. His diagnoses also include thoracic disc protrusion T5-6 and T7-8-9, Lumbar disc protrusion L2-3-4-5 and S1. In the provider notes of 08-12-2015, the injured worker complains of no noticeable improvement with chiropractic care, and he remains symptomatic. He walks with a non-antalgic gait and can heel and toe walk without problems. On examination of the cervical spine, there is satisfactory range of motion without discomfort and no paravertebral tenderness. There is tenderness to palpation in the upper, mid, and lower paravertebral muscles of the thoracic spine. The shoulders have satisfactory range of motion and a negative impingement sign bilaterally. On examination of the right shoulder girdle, there is periscapular and trapezius tenderness with no winging. There is no bony tenderness, and there is a negative Tinel's sign over the brachial plexus and thoracic outlet. The lumbar spine has tenderness to palpation in the upper, mid, and lower paravertebral muscles. Range of motion is diminished in all planes. There is pain with motion, and a list with lumbar motion. Straight leg raising and rectus femoris stretch do not demonstrate nerve irritability. The hips and pelvis have no tenderness to palpation. The calves have a negative Homan's sign. The worker was taking Tramadol 50 since 05-01-2015. In the exam of 04-23-2015, the worker denies history of ulcers or gastritis. He was returned to work with restrictions on 05-22-2015. A request for authorization was submitted for: 60 tablets of Anaprox 550mg, 60 tablets of Tylenol #3 300-30mg, and 30 tablets of Protonix 20mg. A utilization review decision 08/24/2015 certified the

request for Tylenol #3, and non-certified the request for Anaprox and non-certified the request for Protonix.

IMR ISSUES, DECISIONS AND RATIONALES

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

60 tablets of Anaprox 550mg: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: With regard to the use of NSAIDs for chronic low back pain, the MTUS CPMTG states "Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another." "Low back pain (chronic): Both acetaminophen and NSAIDs have been recommended as first line therapy for low back pain. There is insufficient evidence to recommend one medication over the other. Selection should be made on a case-by-case basis based on weighing efficacy vs. side effect profile." Per progress report dated 8/12/15, it was noted, "On examination of the lumbar spine, there is tenderness to palpation in the upper, mid and lower paravertebral muscles. The range of motion is flexion to 15 degrees, 15 degrees Right Lateral Bending, 20 degrees Left lateral bending, 20 degrees Right Lateral Rotation, 20 degrees Left Lateral Rotation and Extension 10 degrees. There is a list with lumbar motion. There is pain with motion. Straight leg raising and rectus femoris stretch sign do not demonstrate any nerve irritability." There was no evidence of an exacerbation of pain or documentation of subjective pain rating. As such, medical necessity cannot be affirmed. Therefore, the request is not medically necessary.

60 tablets of Tylenol #3 300-30mg: Upheld

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

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 reveals no documentation to support the medical necessity of Tylenol #3 nor any documentation addressing the '4 A's' domains, which is a recommended practice for the ongoing 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, medical necessity cannot be affirmed.

Therefore, the request is not medically necessary.

30 tablets of Protonix 20mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic) - 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.