

Case Number:	CM15-0028216		
Date Assigned:	02/20/2015	Date of Injury:	06/01/2007
Decision Date:	04/10/2015	UR Denial Date:	01/14/2015
Priority:	Standard	Application Received:	02/13/2015

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: Arizona, Michigan
 Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 46 year old male, who sustained an industrial injury on 06/01/2007. Medical records provided by the treating physician did not indicate the injured worker's mechanism of injury. Diagnoses include status post posterior lumbar interbody fusion at lumbar four to sacral one, status post cervical three to four, cervical five to six total disc replacement, status post total disc replacement at lumbar five to sacral one, status post left knee arthroscopy with debridement, degeneration of cervical intervertebral disc, cervical disc displacement, and cervical radiculitis. Treatment to date has included x-rays, above listed surgeries, and medication regimen. In a progress note dated 12/10/2015 the treating provider reports constant, severe pain to the low back that is rated a five on the scale of one to ten; sharp, constant cervical spine pain with radiation to the upper extremities along with associated headaches and tension between the shoulder blades with the pain rated as an eight on the scale of one to ten; and intermittent, throbbing pain to the left knee with associated symptoms of swelling and buckling and a pain rating of a five on the scale of one to ten. The treating physician requested medications for symptomatic relief but the documentation provided did not indicate the specific medications being requested. On 01/14/2015, Utilization Review non-certified the requested treatments of Fenoprofen Calcium (Nalfon) 400mg one (1) three times a day with a quantity of 120, Omeprazole 20mg one (1) every twelve hours with a quantity of 120, Ondansetron 8mg oral disintegrating tablets with a quantity of 30, Cyclobenzaprine Hydrochloride 7.5mg, one (1) every eight hours for a quantity of 120, Tramadol ER 150mg one (1) daily for quantity of 90, and Levofloxacin 750mg, one (1) daily times seven days for a quantity of 30, noting the Medical

Treatment Utilization Schedule, Chronic Pain Medical Treatment Guidelines; Official Disability Guidelines Treatment In Workers' Compensation, Pain Procedure Summary (last updated on 12/31/2014); and "Sanford Guide to Antimicrobial Therapy, 2013, 43th Edition."

IMR ISSUES, DECISIONS AND RATIONALES

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

Fenoprofen calcium (Nalfon) 400mg #120: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAID's Page(s): 67 and 68.

Decision rationale: Per the MTUS, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with Naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. A review of the injured workers medical records that are available to me reveal subjective and objective documentation of the injured workers pain and the use of an NSAID would be appropriate in the injured worker, therefore the request for Fenoprofen calcium (Nalfon) 400mg one (1) TID #120 is medically necessary.

Omeprazole 20mg #120: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs - GI symptoms & cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68 and 69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)Proton Pump Inhibitors (PPIs).

Decision rationale: Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria 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). Per the ODG, PPI's are recommended for patients at risk for gastrointestinal events. Prilosec (Esomeprazole), Prevacid

(Lansoprazole) and Nexium (Esomeprazole Magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. In this RCT Omeprazole provided a statistically significantly greater acid control than Lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including Omeprazole (Nexium), Lansoprazole (Prevacid), Omeprazole (Prilosec), Pantoprazole (Protonix), Dexlansoprazole (Dexilant), and Rabeprazole (Aciphex). (Shi, 2008) A trial of Omeprazole or Lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. A review of the injured workers medical records that are available to me reveal subjective and objective documentation of the injured workers pain and the use of an NSAID would be appropriate in the injured worker, therefore the prophylactic use of Omeprazole is medically necessary.

Ondansetron 8mg ODT #30: 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) Antiemetics (for opioid nausea).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Antiemetics (for opioid nausea).

Decision rationale: The MTUS/ ACOEM did not specifically address the use of Ondansetron in the injured worker therefore other guidelines were consulted. Per the ODG Ondansetron is not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) Ondansetron (Zofran): This drug is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and

radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA approved for gastroenteritis. A review of the injured workers medical records does not clarify if this request was for post-operative use or for the treatment of opioid induced nausea and without this information medical necessity cannot be established. Therefore, this request is not medically necessary.

Cyclobenzaprine Hydrochloride 7.5mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Muscle relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41 and 42.

Decision rationale: Per the MTUS, Cyclobenzaprine is recommended as an option in the treatment of chronic pain using a short course of therapy. It is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment suggesting that shorter courses may be better. Treatment should be brief. A review of the injured workers medical records reveal that he has been on Cyclobenzaprine long term which is not consistent with the guideline recommendations, therefore based on the guidelines the request for Cyclobenzaprine 7.5mg, one (1) q 8 hrs #120 is not medically necessary.

Tramadol ER 150mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Per the MTUS, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of opioids should be regularly reassessed. In the injured workers medical records that are available to me, there was no documentation of improved functioning and pain per the MTUS criteria for on-going management, therefore the request for Tramadol ER 150mg one (1) QD #90 is not medically necessary.

Levofloxacin 750mg #30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Infectious Diseases. Levofloxacin (Levaquin) and Other Medical Treatment Guidelines Physicians Desk Reference (PDR) Levaquin (Levofloxacin).

Decision rationale: The MTUS/ ACOEM did not specifically address the use of levofloxacin in the injured worker therefore other guidelines were consulted. Per the ODG levofloxacin is recommended as first-line treatment for osteomyelitis, chronic bronchitis, and pneumonia (CAP), per the PDR it is also used in the treatment of uncomplicated and complicated skin and skin structure infections (SSSIs). A review of the injured workers post-operative visit reports that the lumbar incision was healing well with no signs of infection or wound dehiscence, there was some cellulitis and erythema around the surgical and staple sites, there was no documentation of osteomyelitis. However there seems to be some discrepancy in the amount prescribed and the amount requested. The prescription is for Levofloxacin 750mg, one (1) QD x 7 days; however the request is for #30 without any reasoning given for why 30 rather than 7 tablets would be necessary in the injured worker. Based on this conflicting information the request for Levofloxacin 750mg, one (1) QD x 7 days #30 is not medically necessary.