

Case Number:	CM14-0106976		
Date Assigned:	09/16/2014	Date of Injury:	04/25/2012
Decision Date:	10/30/2015	UR Denial Date:	06/16/2014
Priority:	Standard	Application Received:	07/10/2014

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 59 year old male with an industrial injury dated 04-24-2012. His diagnoses included status post cervical 4 to cervical 7 anterior cervical discectomy and fusion and lumbar discopathy segmental instability. He presented on 01-21-2014 post-surgery reporting improvement in overall symptomatology and no further radicular pain component. On 02-04-2014 and 02-25-2014 progress note indicates persistent pain of the neck and low back. Physical exam noted tenderness at the cervical paravertebral muscles and upper trapezial muscles. There was tenderness at the lumbar paravertebral muscles and pain with terminal motion. Seated nerve root test was positive. There was dysesthesia at the lumbar 5 and sacral 1 dermatomes. In the progress note dated 04-29-2014, the provider noted the injured worker presented with migraine headaches and low back pain. Lumbar spasm was present. The remainder of the note is difficult to decipher. On 06-05-2014, the provider documented: "The patient suffered from an acute exacerbation of severe pain related to a chronic orthopedic condition. The use of opioids in the past has decreased similar acute flare-ups with the patient demonstrating improvement in function." X-ray of the cervical spine dated 02-04-2014(as documented by the provider) failed to reveal any implant/hardware failure. Prior treatment included physical therapy and medications. In a request for authorization dated 04-17-2014, the following medications were requested: Naproxen, Cyclobenzaprine Hydrochloride, Ondansetron ODT, Omeprazole, Tramadol ER and Terocin patches. The request for authorization dated 06-09-2014 is for Naproxen Sodium Tablets 550 mg # 100, Orphenadrine Citrate ER 100 mg (Norflex) # 120, Sumatriptan Succinate Tablets 25 mg # 9 x 2; Ondansetron ODT tablets # 30 x 2 quantity 60, Omeprazole 20 mg # 120,

Tramadol Hydrochloride ER 150 mg # 90 and Terocin patches. The utilization review dated 06-16-2014 the request for Naproxen Sodium 550 mg # 100, Orphenadrine Citrate ER 100 mg (Norflex) # 120, Ondansetron ODT # 30 x 2 quantity 60, Omeprazole 20 mg # 120, Tramadol Hydrochloride ER 150 mg # 90 and Terocin patches was non - certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen Sodium Tablets 550mg #120: Overturned

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): NSAIDs (non-steroidal anti-inflammatory drugs).

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 worker medical records that are available to me reveal that the injured worker had chronic moderate pain in the cervical and lumbar spine, was status post spine surgery and appeared to be having an exacerbation, the use of an NSAID appears appropriate, therefore the request for Naproxen Sodium Tablets 550mg #120 is medically necessary.

Omeprazole 20mg #120: 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): NSAIDs, GI symptoms & cardiovascular risk. 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, PPIs are "Recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), 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. (Donnellan, 2010) 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 esomeprazole (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. (AHRQ, 2011)" A review of the injured workers medical records do not reveal any past or present GI complaints, the injured worker is not at increased risk for a gastrointestinal event according to guideline criteria, therefore the request for Omeprazole 20mg #120 is not medically necessary.

Ondansetron ODT tablets 8mg #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) Treatment in Workers Compensation Pain Procedure Summary.

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 did not reveal an FDA approved rationale for the use of this medication, neither was there any documentation of symptoms or symptomatic benefit that would warrant the continued use of this medication. Therefore, the request for Ondansetron ODT tablets 8mg #30 is not medically necessary.

Orphenadrine Citrate ER 100mg #120: Overturned

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): Muscle relaxants (for pain).

Decision rationale: The MTUS Recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. A review of the injured worker medical records that are available to me reveal that the injured worker had chronic moderate pain in the cervical and lumbar spine, was status post spine surgery and appeared to be having an exacerbation, with documentation of lumbar spasm, the use of a muscle relaxer appears appropriate, therefore the request for Orphenadrine Citrate ER 100mg #120 is medically necessary.

Tramadol Hydrochloride ER 150mg #90: Overturned

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, specific drug list, Opioids, criteria for use.

Decision rationale: The MTUS states that tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. Opioids are recommended for chronic pain, especially neuropathic pain that has not responded to first line recommendations like antidepressants and anticonvulsants. Long term users should be reassessed per specific guideline recommendations and the dose should not be lowered if it is working. Per the MTUS,

Tramadol is indicated for moderate to severe pain. A review of the injured worker medical records that are available to me reveal that the injured worker had chronic moderate pain in the cervical and lumbar spine, was status post spine surgery and appeared to be having an exacerbation, the use of tramadol appears appropriate, therefore the request for Tramadol Hydrochloride ER 150mg #90 is medically necessary.

Terocin patch#30: 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): Topical Analgesics.

Decision rationale: Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed, Therefore the request for Terocin patches is not medically necessary.