

Case Number:	CM15-0065736		
Date Assigned:	04/16/2015	Date of Injury:	07/07/2009
Decision Date:	06/23/2015	UR Denial Date:	03/24/2015
Priority:	Standard	Application Received:	04/07/2015

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: 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 38 year old male who sustained an industrial injury on 07/07/2009. Diagnoses include chronic low back pain with bilateral lower limb radiculitis secondary to 2 level disc herniations at L4-5, and L5-S1, muscle guarding pain, insomnia, impotence from chronic pain, and depression and anxiety form pain. Treatment to date has included diagnostic studies, medications, aquatic physical therapy, acupuncture, and 4 epidural injections. A physician progress note dated 03/11/2015 documents the injured worker has complaints of chronic continuous moderate to high severity pain affecting his back and legs, left side worse than right. He reports much better pain relief and functional improvement with the use of Dilaudid compared to the Norco. Analgesia efficacy is rated 50% with combination of Dilaudid with Neurontin. Sedation and adverse reactions are minimal. Activity level is increased to 50 % with standing, bending, and sitting tolerance improved at least 25%. Pain is rated 5 out of 10 with medications, and 8-9 out of 10 without medications. There is palpable spasm on muscle fullness from L4-5 of the lumbosacral junction. Lumbar range of motion is restricted. Straight leg raise is positive at 30 degrees. He stands with difficulty and gait is wide based, slow, and mildly unsteady. Treatment requested is for 1 prescription for Celebrex 200mg, 1 prescription for Flexeril 7.5mg, 1 prescription for Gabapentin 600mg, 1 prescription for Omeprazole 20mg, Dilaudid 4mg #150, Lunesta 3mg #30, and Zofran 4mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Dilaudid 4mg #150: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96 (78, 89, 95).

Decision rationale: Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation 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 maintenance phase the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. It is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. A review of the injured workers medical records reveal documentation of improved pain and function with the use of Dilaudid according to MTUS recommendations for ongoing management and the continued use of Dilaudid 4mg #150 is medically necessary.

1 prescription for Gabapentin 600mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AED's) Page(s): 16-22.

Decision rationale: Per the MTUS, antiepilepsy drugs are recommended for neuropathic pain. Gabapentin is considered first line treatment for neuropathic pain. The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. A review of the injured workers medical records reveal documentation of improvement in sciatica with no side effects and the continued use of gabapentin may have been appropriate; unfortunately, the request is not accompanied by a quantity and without this information is not medically necessary.

1 prescription for Celebrex 200mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs , NSAIDs, GI symptoms and Cardiovascular risk Page(s): 67-68, 68-69.

Decision rationale: Per the MTUS, NSAIDs and COX-2 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. (Chen, 2008) (Laine, 2008) 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 this. A review of the injured workers medical records do not reveal current or past history of gastrointestinal symptoms and he does not appear to be at increased risk for a GI event, there is no clear rationale for why this is the preferred NSAID and the continued use is not medically necessary.

1 prescription for Omeprazole 20mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. 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 (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 that are available to me do not reveal that he is at increased risk for a gastrointestinal event and the continued use of Omeprazole is not medically necessary.

1 prescription for Flexeril 7.5mg: Upheld

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

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

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. Treatment is not recommended for longer than 2-3 weeks. A review of the injured workers medical records does reveal objective findings of muscle spasm, and the medication is being prescribed for use as necessary, however the request is not accompanied by a quantity, and therefore is not medically necessary.

Lunesta 3mg #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)- Pain (Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness and Stress / Eszopicolone (Lunesta).

Decision rationale: The MTUS did not specifically address the use of lunesta, therefore other guidelines were consulted. Per the ODG, "Not recommended for long-term use, but recommended for short-term use. See Insomnia treatment. See also the Pain Chapter. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. In this study, eszopicolone (Lunesta) had a Hazard ratio for death of 30.62 (C.I., 12.90 to 72.72), compared to zolpidem at 4.82 (4.06 to 5.74). In general, receiving hypnotic prescriptions was associated with greater than a threefold increased hazard of death even when prescribed less than 18 pills/year. (Kripke, 2012) The FDA has lowered the recommended starting dose of eszopiclone (Lunesta) from 2 mg to 1 mg for both men and women. Previously recommended doses can cause impairment to driving skills,

memory, and coordination as long as 11 hours after the drug is taken. Despite these long-lasting effects, patients were often unaware they were impaired." A review of the injured workers medical records do not reveal extenuating circumstances that would warrant deviating from the guidelines, therefore the request for lunesta is not medically necessary.

Zofran 4mg #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), Pain (Chronic).

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. The use of zofran is not supported by the guidelines in the treatment of opioid induced nausea and a review of the injured workers medical records do not show any extenuating circumstances that would warrant deviating from the guidelines, therefore the request for Zofran is not medically necessary.