

Case Number:	CM15-0201218		
Date Assigned:	10/16/2015	Date of Injury:	12/03/2014
Decision Date:	12/22/2015	UR Denial Date:	10/08/2015
Priority:	Standard	Application Received:	10/13/2015

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:

This injured worker is a 47 year old female who reported an industrial injury on 12-3-2014. Her diagnoses, and or impressions, were noted to include: knee sprain-strain of the cruciate and medial ligaments of knee; and tear of the medial meniscus and "ACL"; "GERD"; sleep disorder; and chronic anxiety. Recent right knee x-rays were done on 5-1-2015, following a mechanical fall; and magnetic imaging studies of the right knee were done on 1-26-2015 (blurry). Her treatments were noted to include: a supplemental "QME" panel evaluation (7-22-15) and report on 9-28-2015; psychiatric evaluation and treatment; medication management; and a return to part-time work with modified work duties. The progress notes of 9-24-2015 reported: better control over her anxiety following teachings from her psychologist about her injury and needed and upcoming surgery; a fall on her right knee with torn "ACL-PCL-MCI-PFL-meniscus", and that it felt unstable and would give-way; that the repair surgery had been authorized for 10-5-2015; and that her medications provided 40-50% relief from pain without side-effects. The objective findings were noted to include: an elevated blood pressure; an antalgic gait; good range-of-motion; positive Drawers and McMurrays tests; tenderness along the joint line; and that she spoke very rapidly. The physician's requests for treatment were noted to include the refilling of Diclofenac 100 mg daily and Omeprazole 20 mg twice a day as needed, and Lunesta 3 mg at hour of sleep as needed (was very helpful). No Request for Authorization (RFA) for Diclofenac 100 mg, #60; Omeprazole 20 mg, #60; Eszopiclone 1 mg, #30; and Eszopiclone 2 mg, #30 was noted in the medical records provided. The Utilization Review of 10-8-2015 non-

certified the request for: Diclofenac 100 mg, #60; Omeprazole 20 mg, #60; Eszopiclone 1 mg, #30; and Eszopiclone 2 mg, #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Eszopiclone 1 mg #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, Pain, Insomnia treatment.

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 / Eszopiclone (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, eszopiclone (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.

Omeprazole 20 mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

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, PPI's are "Recommended for patients at risk for gastrointestinal events. 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 reveal a diagnosis of GERD, a PPI is appropriate treatment in this setting, therefore the request for Omeprazole 20 mg #60 is medically necessary.

Eszopiclone 2 mg #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, Pain, Insomnia treatment.

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 / Eszopiclone (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, eszopiclone (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.

Diclofenac 100 mg #60: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steriodal 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 workers medical records reveal documentation of 40-50% improvement in pain with the use of medication which include Diclofenac, continued use appears appropriate and therefore the request for Diclofenac 100 mg #60 is medically necessary.