

Case Number:	CM15-0182690		
Date Assigned:	09/23/2015	Date of Injury:	06/26/2013
Decision Date:	11/19/2015	UR Denial Date:	09/09/2015
Priority:	Standard	Application Received:	09/16/2015

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 59-year-old female, with a reported date of injury of 06-28-2013. The diagnoses include status postoperative open reduction and internal fixation fracture proximal right humerus, severe adhesive capsulitis bilateral shoulders, cervical strain, lumbar strain, possible internal derangement with possible lateral meniscal tear, right knee, knee sprain with patellofemoral inflammation and knee joint inflammation, chronic pain associated with depression, anxiety, stress, insomnia, gastritis, and weight gain of 10 pounds, and mild bilateral carpal tunnel syndrome. Treatments and evaluation to date have included wrist brace, TENS unit, a neck pillow, Tramadol, Trazodone (since at least 03-2015), Naproxen (since at least 04-2015), Protonix (since at least 03-2015), Lunesta (since at least 07-2015), and Maxalt (since at least 07-2015). The diagnostic studies to date have not been included in the medical records provided. The medical report dated 08-31-2015 indicates that the injured worker had an element of depression, issues with gastrointestinal (GI) irritation, issues with sleep, and issues with anxiety. She reported limited motion in both shoulders, pain along the right knee on the outer aspect, and neck pain with radiation to the shoulder blade. It was noted that an MRI of the right shoulder on 01-25-2015 showed no rotator cuff tear and simple impingement; and electrodiagnostic studies in 09-2014 showed bilateral carpal tunnel syndrome, but no radiculopathy. The treating physician documented that a repeat 10-panel urine screen "confirmed that she is taking the Tramadol, the first one being negative." The injured worker's pain levels were not documented in the medical report. The objective findings include tenderness along the facets with positive facet loading along the neck; tenderness along the

shoulder on the right side with no more than 90 degrees of motion in abduction or flexion bilaterally, restrictions being more on the right than the left; and tenderness along the knee laterally with good range of motion. The treatment plan included Naproxen, Trazodone, Lunesta, Maxalt, and Protonix. The injured worker officially retired in 04-2014, and was made permanent and stationary in 05-2015. The work status indicated that the injured worker shoulder avoid reaching at shoulder level; forceful pushing, pulling, and lifting; repetitive motion of the shoulder; repetitive motion of the wrist and hand; and forceful gripping, grasping, and torquing. The request for authorization was dated 08-31-2015. The treating physician requested Naproxen 550mg #60, Trazodone 50mg #60, Protonix 20mg #60, Lunesta 2mg #30, and Maxalt 10mg #12. On 09-09-2015, Utilization Review (UR) non-certified the request for Naproxen 550mg #60, Trazodone 50mg #60, Protonix 20mg #60, Lunesta 2mg #30, and Maxalt 10mg #12.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen 550mg qty: 60: 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 (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. Unfortunately a review of the injured workers medical records do not show improvement in pain and function with the use of this medication, medical necessity for continued use is not established, therefore the request for Naproxen 550mg qty: 60 is not medically necessary.

Trazodone 50mg qty: 60: 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' Comp, 9th edition (web).

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 / Trazodone.

Decision rationale: The MTUS /ACOEM did not specifically address the use of trazodone therefore other guidelines were consulted. Per the ODG, trazodone is recommended as an option for insomnia, only for patients with potentially coexisting mild psychiatric symptoms such as depression or anxiety. Trazodone was approved in 1982 for the treatment of depression. It is unrelated to tricyclic or tetracyclic antidepressants and has some action as an anxiolytic. Off-label uses include alcoholism, anxiety, insomnia, and panic disorder. Although approved to treat depression, the American Psychiatric Association notes that it is not typically used for major depressive disorder. Over the period 1987 through 1996, prescribing trazodone for depression decreased throughout the decade, while off-label use of the drug for insomnia increased steadily until it was the most frequently prescribed insomnia agent. Unfortunately, a review of the injured workers medical records do not show improvement in pain and function with the use of this medication, medical necessity for continued use is not established, therefore the request for Trazodone is not medically necessary.

Protonix 20mg qty: 60: 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 that are available does not reveal that the injured worker is at increased risk for a gastrointestinal event as there is no current or past history of gastrointestinal complaints, therefore the request for Prilosec is not medically necessary.

Lunesta 2mg qty: 30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Treatment in Workers' Comp, 9th edition (web).

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 eszopicolone (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.

Maxalt 10mg qty: 12: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physician's Drug Reference (PDR).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Head / rizatriptan.

Decision rationale: The MTUS / ODG did not address the use of triptans, therefore other guidelines were consulted. Per the ODG it is 'recommended for migraine sufferers. Rizatriptan (Maxalt) is a triptan drug developed by ██████████ for the treatment of migraine headaches. Meta-analyses of double-blind placebo-controlled studies have confirmed the superior efficacy of rizatriptan. (Gbel, 2010) While the Maxalt brand of rizatriptan therapy is more expensive than other triptans, savings can be expected in reduced migraine-related loss of work productivity compared with less effective treatments. (Mullins, 2007) (McCormack, 2005) According to the FDA Orange Book, equivalent generics have been approved for Maxalt, so generic rizatriptan would be recommended. (FDA, 2013) However, a review of the injured workers medical records that are available do not reveal a clear rationale for the use of this medication, without this information medical necessity is not established, therefore the request for Maxalt is not medically necessary.