

<b>Case Number:</b>	CM15-0146963		
<b>Date Assigned:</b>	08/07/2015	<b>Date of Injury:</b>	09/01/1998
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	07/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/28/2015

### 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: California

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 60 year old female, who sustained an industrial injury on 9-1-1998. Diagnoses have included bilateral knee pain and bilateral elbow pain. Treatment to date has included bilateral ulnar nerve transposition (1998), bilateral knee replacements (left 2000, right 2001), transcutaneous electrical nerve stimulation (TENS), a home exercise program and medication. According to the progress report dated 6-26-2015, the injured worker complained of bilateral elbow pain and bilateral knee pain. She rated her pain with medications as 4.5 out of 10. She rated her pain without medications as eight out of ten. She reported that medications were working well. The injured worker had an antalgic gait, assisted by a walker. Exam of the elbows revealed tenderness and restricted range of motion. Exam of the right hand revealed painful, restricted range of motion and tenderness to palpation. Exam of the knees revealed tenderness to palpation and mild effusion. Authorization was requested for Ambien, Lyrica, Pennsaid, Celexa, Norco and laboratory tests: BUN, creatinine and hepatic function panel.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**One bun/creatinine test:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, specific drug list & adverse effects.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, Specific Drug List & Adverse Effects Section Page(s): 70.

**Decision rationale:** Per MTUS guidelines, NSAIDs are recommended with cautions below. Disease-State Warnings for all NSAIDs: All NSAIDs have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. Other disease-related concerns (non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDs. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. Overall Dosing Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. In this case, the associated request for NSAIDs is not supported, therefore there is no indication for periodic lab monitoring. The request for one bun/creatinine test is determined to not be medically necessary.

**One hepatic function panel:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, Specific Drug List & Adverse Effects Section Page(s): 70.

**Decision rationale:** Per MTUS guidelines, NSAIDs are recommended with cautions below. Disease-State Warnings for all NSAIDs: All NSAIDs have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. Other disease-related concerns (non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise

renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended. Overall Dosing Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. In this case, the associated request for NSAIDs is not supported, therefore there is no indication for periodic lab monitoring. The request for one hepatic function panel is determined to not be medically necessary.

**Ambien 10mg #20 with 1 refill:** 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): Zolpidem (Ambien) (2015).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Insomnia Section.

**Decision rationale:** The MTUS Guidelines do not address the use of zolpidem. Per the Official Disability Guidelines, pharmacological agents should only be used for insomnia management after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically whereas secondary insomnia may be treated with pharmacological and/or psychological measures. Zolpidem reduces sleep latency and is indicated for the short-term treatment (7-10 days) of insomnia with difficulty of sleep onset and/or sleep maintenance. Adults who use zolpidem have a greater than 3-fold increased risk for early death. Due to adverse effects, FDA now requires lower doses for zolpidem. The dose for women should be reduced from 10 mg to 5 mg for immediate release products and from 12.5 mg to 6.25 mg for extended release products. The medical records do not address the timeline of the insomnia or evaluation for the causes of the insomnia. The injured worker has taken Ambien since at least June, 2012 without subjective improvement with sleep. The medical records do not indicate that non-pharmacological modalities such as cognitive behavioral therapy or addressing sleep hygiene practices prior to utilizing a pharmacological sleep aid. The request for Ambien 10mg #20 with 1 refill is determined to not be medically necessary.

**Lyrica 25mg #90 with 1 refill:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs (AEDs) Section Page(s): 16-20.

**Decision rationale:** The MTUS Guidelines support the use of Lyrica for the treatment of diabetic neuropathy and postherpetic neuralgia. Lyrica has been found to be safe and efficacious to treat pain and other symptoms. Lyrica is FDA approved for fibromyalgia. In this case, there is no objective evidence of neuropathic pain, therefore the request for Lyrica 25mg #90 with 1 refill is determined to not be medically necessary.

**Pennsaid 1.5% solution #1 with 1 refill:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain: Pennsaid (diclofenac sodium topical solution) 2015.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Pennsaid (Diflofenac Sodium Topical Solution) Section.

**Decision rationale:** Per the MTUS Guidelines, the use of topical analgesics is recommended as an option for some agents. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Per the ODG, Pennsaid is not recommended as a first-line treatment. Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, and after considering the increased risk profile with diclofenac, including topical formulations. In studies Pennsaid was as effective as oral diclofenac, but was much better tolerated. FDA approved Pennsaid Topical Solution in 2009 for the treatment of the signs and symptoms of osteoarthritis of the knee, and the FDA requires a Risk Evaluation and Mitigation Strategy (REMS) from the manufacturer to ensure that the benefits of this drug outweigh its risks. In this case, the injured worker has been using this medication since January, 2015 although there is no indication that the injured worker has been diagnosed with osteoarthritis. The request for Pennsaid 1.5% solution #1 with 1 refill is determined to not be medically necessary.