

<b>Case Number:</b>	CM15-0140574		
<b>Date Assigned:</b>	08/04/2015	<b>Date of Injury:</b>	01/04/2001
<b>Decision Date:</b>	10/02/2015	<b>UR Denial Date:</b>	07/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/20/2015

### 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 57-year-old male, who sustained an industrial injury on January 4, 2001. He reported lumbar back pain and left knee pain and poor sleep. The injured worker was diagnosed as having osteoarthritis of the knee; status post left knee surgery, post lumbar laminectomy syndrome, lumbar radiculopathy, lumbar facet syndrome and knee pain. Treatment to date has included diagnostic studies, surgical intervention of the lumbar spine, surgical intervention of the knee, conservative therapies, physical therapy, aqua therapy, lumbar epidural steroid injections, lumbar facet injection, trigger point injection, TENS unit, home exercises, heat, ice and rest, medications and work restrictions. Currently, the injured worker continues to report lumbar back pain and left knee pain and poor sleep. The injured worker reported an industrial injury in 2001, resulting in the above noted pain. He was treated conservatively and surgically without complete resolution of the pain. Evaluation on January 15, 2015, revealed continued pain as noted. He rated his pain at 7.5 on a 1-10 scale with 10 being the worst while using medications and 10 on a 1-10 scale without the use of medications. He noted his quality of sleep is poor and his activity level has decreased. It was noted the injured worker was taking the medications as directed. He noted the medications were now less effective since he started an opioid taper. Current medications included Alprazolam, Xanax, Carisoprodol, DHEA, Duloxetine, Famotidine, Gabapentin, Hydrocodone-Acetaminophen, Ibuprofen and Pennsaid. It was noted Electrodiagnostic studies revealed chronic lumbar radiculopathy. Urinary drug screen on June 27, 2014, was noted to reveal results inconsistent with expectations during the weaning of opioids phase. It was noted he had been weaned from benzodiazepines. He deferred physical

therapy secondary to poor previous results. Evaluation on February 12, 2015, revealed continued pain as noted. It was noted the injured worker insisted the radiculopathy of the lower extremity with associated tingling and numbness is secondary to previous left total knee arthroscopy. Evaluation on March 26, 2015, revealed continued severe left knee pain rated at 7 on a 1-10 scale with 10 being the worst with the use of medications. It was noted he was being weaned from Soma. He noted continued poor sleep secondary to muscle spasms and requested another medication. Zanaflex was prescribed for a trial. Evaluation on June 18, 2015, revealed continued pain as noted. He continued to rate his pain at 7 on a 1-10 scale with the use of medications and 10 on a 1-10 scale with 10 being the worst without the use of medications. He noted his quality of sleep was poor. He reported Zanaflex was not helping. It was noted the injured worker refused to give urine for a routine urinary drug screen. He reported no benefit with previous aqua therapy, physical therapy, pain injections, surgical interventions and Zanaflex. DHEA 25mg #30 with 1 refill, Duloxetine HCL DR 60mg #30 with 1 refill, Famotidine 40mg #30 with 1 refill, Gabapentin 300mg #120 with 1 refill, Hydrocodone-Acetaminophen 10/325mg #60 with 1 refill, Ibuprofen 600mg #90 with 1 refill, Pennsaid 1.5% solution #1 with 1 refill and Zanaflex 4mg with 1 refill were requested.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Hydrocodone-Acetaminophen 10/325mg #60 with 1 refill: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Page(s): 74-96.

**Decision rationale:** According to the California (CA) MTUS Guidelines Hydrocodone-acetaminophen is an opioid analgesic recommended after a trial of a first line oral analgesic has failed. Guidelines offer very specific requirements for the ongoing use of opiate pain medication to treat chronic pain. Recommendations state the lowest possible dose is used as well as "ongoing review and documentation of pain relief, functional status, appropriate medication use and its side effects." It also recommends that providers of opiate medication document the injured worker's response to pain medication including the duration of symptomatic relief, functional improvements, and the level of pain relief with the medications. It was indicated in the documentation use of the prescribed opioid medication did not decrease the level of pain the injured worker reported from one visit to the next. In addition, there was no noted functional improvement or improved pain noted during the duration of the prescription for Hydrocodone-acetaminophen. For these reasons, the request is not medically necessary.

**Duloxetine HCL DR 60mg #30 with 1 refill: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cymbalta (Duloxetine) Page(s): 43-44.

**Decision rationale:** According to the California (CA) MTUS Guidelines, Cymbalta is a norepinephrine and serotonin reuptake inhibitor (SNRI) anti-depressant recommended as a first line option to treat neuropathic pain and depression. The CA MTUS does not support the use of Cymbalta for chronic pain secondary to lumbar radiculopathy. It was noted the injured worker had been treated with Cymbalta for an extended period of time with continued reports of depression and anxiety. There is insufficient evidence of the medication's effectiveness. The request is not medically necessary.

**Ibuprofen 600mg #90 with 1 refill:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 61-73.

**Decision rationale:** According to the California (CA) MTUS Guidelines, Ibuprofen is a nonsteroidal anti-inflammatory (NSAID) used as an option for short-term symptomatic relief. The CA MTUS recommends the use NSAIDs at the lowest dose possible for the shortest period of time to achieve effectiveness for the individual. In this case, the injured worker had been prescribed the NSAID for over one year with no indication of improved pain or increased function. In addition, the injured worker continued to require work restrictions. Furthermore, the amount of the NSAID prescribed indicated the intention of long-term use. For these reasons, the request is not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** Per the California (CA) MTUS Guidelines, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The CA MTUS notes topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. In this case, there was no indication of failed first line therapy trials. In addition, the injured worker had been prescribed the medication for months with no noted decrease in pain levels or increase in activity levels. For these reasons, the request is not medically necessary.

**Gabapentin 300mg #120 with 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16.

**Decision rationale:** According to the California (CA) MTUS Guidelines, Gabapentin is shown to be effective for the treatment of diabetic neuropathy and post-herpetic neuralgia and has been considered a first line treatment for neuropathic pain. The documentation provided did not include evidence of improved function or documentation of efficacy of the medication. Ongoing assessments of pain and function supported with tools of measurement were provided and indicated no improvement in the intensity of the pain. For these reasons, the request is not medically necessary.

**Famotidine 40mg #30 with 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

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

**Decision rationale:** According to the California (CA) MTUS Guidelines, Famotidine is a histamine-2 blocker recommended for the treatment of gastrointestinal events in individuals with no cardiovascular disease. It is intended to protect the gastrointestinal tract with the concurrent use of NSAIDS. In this case, there is no indication of gastrointestinal problems. In addition, there was no indication of failed first line therapies with proton pump inhibitors. The request is not medically necessary.

**DHEA 25mg #30 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.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) / Dehydroepiandrosterone (DHEA).

**Decision rationale:** The MTUS / ACOEM Guidelines did not address the use of DHEA, therefore other guidelines were consulted. Per the ODG, DHEA is recommended as an option in older women at risk for spinal bone mineral density losses. This RCT concluded that dehydroepiandrosterone (DHEA) supplementation in older women, but not in men, improves spine bone mineral density (BMD) when co-administered with vitamin D and calcium. In men, no difference between groups occurred in any BMD measures or in bone turnover markers during year 1 or year 2. The free testosterone index and estradiol increased in the DHEA group

only. In women, spine BMD increased by 1.7 +/- 0.6% during year 1 and by 3.6 +/- 0.7% after 2 years of supplementation in the DHEA group; however, in the placebo group, spine BMD was unchanged during year 1 but increased to 2.6 +/- 0.9% above baseline during year 2 after the crossover to DHEA. A review of the injured workers medical records that are available to me do not reveal a clear rationale or indication for the use of this medication and without this information, medical necessity is not established, therefore the request is not medically necessary.

**Zanaflex 4mg with 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 299.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine (Zanaflex) Page(s): 63-66.

**Decision rationale:** According to the California MTUS Guidelines, Zanaflex is a centrally acting alpha2-adrenergic agonist that is approved for the management of spasticity and has an off label use for low back pain. The injured worker consistently reported increasing pain with a history of surgical intervention of the lumbar spine and left knee. There was indication of improvement from one visit to the next as a result of continuing Zanaflex. The injured worker reported wanting to continue Soma secondary to Zanaflex being ineffective. It was also noted he continued to have poor sleep. The request is not medically necessary.