Case Number:	CM15-0179603		
Date Assigned:	09/21/2015	Date of Injury:	03/04/2013
Decision Date:	11/12/2015	UR Denial Date:	08/12/2015
Priority:	Standard	Application Received:	09/11/2015

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: Emergency 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 40 year old female, who sustained an industrial injury on 3-04-2013. The injured worker was diagnosed as having chronic pain, other, cervical radiculitis, anxiety, complex regional pain syndrome, right upper extremity, and rule out right upper extremity thoracic outlet syndrome. She was also being treated for major depressive disorder and generalized anxiety disorder. Treatment to date has included diagnostics, right stellate ganglion block, right shoulder manipulation under anesthesia 5-2014, acupuncture, physical therapy, psychological treatment, and medications. On 2-11-2015, the injured worker reported neck and right upper extremity pain, rated 6 out of 10 with medications and 8 out of 10 without. She was recommended urine toxicology (results not documented), Vitamin D level. She was to continue Gabapentin 600mg (one-half tablet twice daily), Naproxen 550mg (1 tablet twice daily), and Norco 10-325mg (1 tablet every 8 hours as needed). Medications noted as prescribed by other physician were documented as Alprazolam, Naproxen, Paroxetine, and Vicodin. Currently (8-04-2015), the injured worker complains of neck and right upper extremity pain, rated 6 out of 10 with medications and 8 out of 10 without. She reported ongoing activities of daily living limitations due to pain in activity, ambulation, hand function, and sleep. She reported medications as helpful, with 50% improvement due to this therapy. Exam of the cervical spine noted spinal vertebral tenderness, range of motion "moderately limited due to pain", increased pain with flexion, extension and rotation, and allodynia in the right inferior forearm. She was unable to perform overhead strength test for Addison test. Upper extremity examination noted tenderness to palpation at the right acromioclavicular joint, right anterior shoulder, the right

upper extremity, and right hand. Motor exam showed "decreased" strength in the right upper extremity. Associated findings included hypersensitivity in the right upper extremity and allodynia and temperature changes in the right upper extremity. Range of motion in the right shoulder was flexion and abduction to 70 degrees with pain. Failed medications documented included "Gabapentin (nausea); Lyrica (nausea)". Insufficient "serum 25 (OH) D levels" were documented as less than 30mg per milliliter. The progress report (3-11-2015) noted that Vitamin D was prescribed. Current medications were to be renewed. Urine toxicology report (collected 5-12-2015) detected only Acetaminophen, Hydromorphone, Tramadol, Norhydrocodone, and Desmethyltramadol. The treatment plan included Norco 10-325mg (1 tab every 8 hours) #90, Vitamin D 2000 units (2 daily) #100, Gabapentin 600mg (one half tablet three times daily) #90, and Naproxen 550mg (twice daily) #60, non-certified by Utilization Review on 8-12-2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg 1 every 8 hours #90: 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): Opioids, criteria for use.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement seen. As such, the request is not certified. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome. Therefore, the request is not medically necessary.

Vitamin D 2000 units 2 every day #100: 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), Forearm, Wrist and Hand, Vitamin D (cholecalciferol).

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)/vitamin D (cholecalciferol).

Decision rationale: The request is for the use of vitamin D. The official disability guidelines state the following regarding its use for chronic pain. Not recommended for the treatment of chronic pain based on recent research below. Although it is not recommended as an isolated pain

treatment, vitamin D supplementation is recommended to supplement a documented vitamin deficiency, which is not generally considered a workers' compensation condition. Musculoskeletal pain is associated with low vitamin D levels but the relationship may be explained by physical inactivity and/or other confounding factors. Adjusting for these factors attenuated the relationship, although pain remained moderately associated with increased odds of 20% of having low vitamin D levels. (McBeth, 2010) Inadequate vitamin D may represent an under-recognized source of nociperception and impaired neuromuscular functioning among patients with chronic pain.Physicians who care for patients with chronic, diffuse pain that seems musculoskeletal - and involves many areas of tenderness to palpation - should consider checking vitamin D level. For example, many patients who have been labeled with fibromyalgia may be suffering from symptomatic vitamin D inadequacy. There is also a correlation between inadequate vitamin D levels and the amount of narcotic medication taken by chronic pain patients. Patients with inadequate vitamin D may benefit from cholecalciferol 50,000 international units dosed according to the level of deficiency, but caution is necessary for patients with calcium- or phosphate- processing disorders because increasing vitamin D levels could be problematic in patients with kidney failure or stones or primary hyperparathyroidism or sarcoidosis. For patients with adequate vitamin D looking to maintain levels, 10 to 15 minutes of sun exposure might be recommended with no sunscreen on the trunk and arms and legs 3 times a week. (Turner, 2008) Recent studies have suggested that vitamin D supplementation is a safe, well-tolerated approach to improve muscle strength and function, leading to fewer falls. This systematic review and meta-analysis demonstrated that there is a protective effect of vitamin D supplementation on fall prevention in older adults. (Kalyani, 2010) On the other hand, most Americans already receive enough vitamin D, according to a report released by the Institute of Medicine, and they concluded that the positive effects of vitamin D haven't been nearly as clear-cut as advocates have suggested. (IOM, 2010) Women who take a single high dose of vitamin D (300,000 IUs) suffer much less menstrual pain and have no need of pain medications for any reason for up to 2 months, according to a new RCT. The authors say vitamin D may act as an anti-inflammatory and may regulate the expression of key genes involved in the prostaglandin pathway, causing decreased biological activity of prostaglandins. Although the numbers were small, there was a convincing difference between the placebo and vitamin D groups in the study, but it is premature to recommend this. The 300,000 IU dose of vitamin D used in the study is probably harmless if taken every month or two, but it could cause hypercalcemia if taken daily. (Lasco, 2012) Recent research: In this RCT, Vitamin D supplementation for 2 years at a dose sufficient to elevate 25-hydroxyvitamin D plasma levels to higher than 36 mg/ml, when compared with placebo, did not reduce knee pain or cartilage volume loss in patients with symptomatic knee OA. (McAlindon, 2013) Optimization of calcifediol levels in fibromyalgia syndrome had a positive effect on the perception of pain, but further studies with larger patient numbers are needed to prove the hypothesis. (Wepner, 2014) In this case, the use of this vitamin for chronic pain is not indicated. As stated above: "Although it is not recommended as an isolated pain treatment, vitamin D supplementation is recommended to supplement a documented vitamin deficiency, which is not generally considered a workers' compensation condition." As such, the request is not certified. Therefore, the request is not medically necessary.

Gabapentin 600mg 1/2 tab three times a day #90: 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): Antiepilepsy drugs (AEDs).

Decision rationale: The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials, which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. There also should be documentation of functional improvement and side effects incurred with use. Disease states, which prompt use of these medications, include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is lack of documentation of adequate pain reduction for continued use. The records also do not reveal functional improvement or screening measures as required. As such, the request is not certified. Therefore, the request is not medically necessary.

Naproxen 550mg twice a day #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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)/NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): 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) Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute

LBP. (Van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009)As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the use of an NSAID is not advised. This is secondary to the duration of use and significant side effect profile. Also, the use of NSAIDs is known to delay the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not certified. Therefore, the request is not medically necessary.