

<b>Case Number:</b>	CM13-0030731		
<b>Date Assigned:</b>	11/27/2013	<b>Date of Injury:</b>	07/15/2006
<b>Decision Date:</b>	01/24/2014	<b>UR Denial Date:</b>	09/11/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/30/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation, and is licensed to practice in California. 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 physician 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/services. He/She is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient states that while she was working on 7/15/06, she was attending an advanced coding class for work. She was crossing the street into the parking structure. There were no signs posted that the ground was wet. She slipped forward landing on her right knee and right arm when she tried to break her fall. She did not feel immediate pain in her right shoulder. She reported it but was unable to get to the doctor that day. She was taking her daughter to college that weekend. Over the weekend the pain worsened in her right arm up to the shoulder as well as her right knee and low back. On Monday she was sent to [REDACTED]. At [REDACTED], she was examined. She cannot recall the exact details. She was given medications and she was given an ACE wrap. She was told she had sprained her wrist. She was placed off of work for two weeks. She did not feel improvement. Her right shoulder worsened but after six weeks she was released to work without restrictions. The patient then retained legal counsel and was referred to [REDACTED]. Since presenting to [REDACTED], she reports undergoing x-rays, magnetic resonance imaging (MRI) and electromyography/nerve velocity studies (EMG/NCV) of her right shoulder, right wrist, right knee and low back. Surgery to the right shoulder was recommended and performed by [REDACTED] in 2007. She was placed off of work and she underwent postoperative physical therapy. She had some improvement in her right upper extremity pain after surgery but her symptoms did not resolve. She was given medications and topical creams for the right shoulder. She has had injections to the right shoulder without improvement. Since the patient has failed to improve with conservative treatment to date, she had now been referred to this examiner for surgical considerations. The patient complains of pain in her right shoulder, which is described as sharp and burning, and is present constantly.

[REDACTED]

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Tizanidine 4mg #120 one PO Q12h PRN with 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Muscle Relaxants (for pain)..

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Antispasmodics Page(s): 66.

**Decision rationale:** The MTUS guidelines indicate that Tizanidine (Zanaflex<sup>®</sup>, generic available) is a centrally acting alpha<sub>2</sub>-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. Eight studies have demonstrated efficacy for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. It may also provide benefit as an adjunct treatment for fibromyalgia. It is recommended to use this medication with caution in renal impairment and should be avoided in hepatic impairment. Tizanidine use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. Besides Tizanidine's unlabelled use for low back pain treatment, there is no documentation of this employee's renal or hepatic function test results in the record reviewed, prior to prescription of this medication. This reviewer considers the prescription of Tizanidine 4mg #120 one po q12 PRN with 3 refills to be not medically necessary.

**Hydrocodone/APAP 10/325mg #60 one PO Q6-8h PRN with 3 refills:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Opioids Page(s): s 76-77.

**Decision rationale:** According to the MTUS guidelines, Norco (hydrocodone (a semi-synthetic opioid which is considered the most potent oral opioid) and Acetamenophen) is Indicated for moderate to moderately severe pain however, the MTUS guidelines stipulate specific criteria to follow before a trial of opioids for chronic pain management. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage chronic pain. These medications are generally classified according to potency and duration of dosage duration. Evidence-based guidelines recommend the use of opioid pain medications for the short-term treatment of moderate to severe pain. Ongoing use of opiate medication may be recommended with documented pain relief, an increase in functional improvement, a return to work and evidence of proper use of the medications. Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. When discontinuing opiate pain medication a slow taper is recommended to wean the patient. Besides, results of studies of opioids for

musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of opioids for severe cases, not to exceed 2 weeks, and do not support chronic use. The MTUS guidelines on Opioids Ongoing Management recommend "Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects." This has not been documented for this employee. The documentation indicates the medication "allows the patient to perform some activities of daily living", but this did not state that there is an increase in functional improvement. Therefore the request for Hydrocodone/APAP 10/325 #60 one p.o. q6-8 hours prn times 3 refills is not medically necessary.

**Xoten-C lotion 0.002/10%/20% 113.4ml, apply a thin layer 2-3 times daily:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Topical Analgesics Page(s): s 28, 111-113.

**Decision rationale:** XOTEN-C is a topical analgesic with the following active ingredients: Methyl salicylate 20%; Menthol USP 10%; Capsaicin 0.002%. It is used for relief of mild pain due to muscular strain, arthritis, and simple back pain. It is recommended for temporary relief of pain. According to the MTUS guidelines, the use of topical analgesics is largely experimental with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists,  $\beta$  agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor. There is little to no research to support the use of many of these agents. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Although the MTUS guidelines made no mention of Menthol as a recommended topical analgesic, the literature search of the Journal of Pharmacology and Experimental Therapeutics Published on September 5, 2012 revealed that Menthol is one of the most commonly used chemicals in our daily life, not only because of its fresh flavor and cooling feeling but also because of its medical benefit. Previous studies have suggested that menthol produces analgesic action in acute and neuropathic pain through peripheral mechanisms. However, the central actions and mechanisms of menthol remain unclear. Recent studies report that menthol has direct effects on the spinal cord. Menthol decreased both ipsilateral and contralateral pain hypersensitivity induced by complete Freund's adjuvant in a dose dependent manner. Menthol also reduced both first and second phases of formalin-induced spontaneous nociceptive behavior. According to the MTUS guidelines, there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. It is not recommended for neuropathic pain and there is no evidence to support its use. Therefore the request for Xoten-C lotion is not medically necessary.

**Tramadol 50mg #60 one PO Q4-6h PRN with 3 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Opioids, Specific Drug List.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section Opioids Page(s): s 75, 80-85.

**Decision rationale:** The MTUS guidelines regarding Tramadol (Ultram), indicates it is one of a small class of synthetic opioids, with opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine as a central acting analgesic. This class of synthetic opioids has been reported to be effective in managing neuropathic pain, with side effects similar to traditional opioids. Opioid efficacy is limited to short term pain relief, and long term efficacy is unclear. Failure to respond to a time-limited course of opioids has led to suggestion of reassessment and consideration of alternative therapy. A recent Cochrane review found that Ultram decreased pain intensity, produced symptom relief and improved function for a time period of up to three months but the benefits were small (a 12% decrease in pain intensity from baseline). Adverse events often caused study participants to discontinue this medication, and could limit usefulness. There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. Short-term use is recommended on a trial basis after there has been evidence of failure of first-line non-pharmacologic and medication options (such as acetaminophen or NSAIDs) and when there is evidence of moderate to severe pain. Opioids are also recommended for a trial if there is evidence of contraindications for use of first-line medications. Weak opioids should be considered at initiation of treatment with this class of drugs (such as Tramadol, Tramadol/acetaminophen, hydrocodone and codeine), and stronger opioids are only recommended for treatment of severe pain under exceptional circumstances (oxycodone, oxycodone, hydromorphone, fentanyl, morphine sulfate). Benefits of opioids are limited by frequent side effects (including nausea, constipation, dizziness, somnolence and vomiting). The MTUS guidelines on Tramadol state that this medication is not recommended as a first-line oral analgesic. The medical records in this case do not provide a rationale as to why this employee requires the use of two short acting analgesic medications. Therefore the request for Tramadol 50mg # 60 PO Q4-6hours PRN with three refills is not medically necessary.