

<b>Case Number:</b>	CM13-0026464		
<b>Date Assigned:</b>	03/19/2014	<b>Date of Injury:</b>	05/07/2007
<b>Decision Date:</b>	05/09/2014	<b>UR Denial Date:</b>	08/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/19/2013

### 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. The expert reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine 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 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/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 is a 54-year-old female with a date of injury of 05/07/2007. The listed diagnoses per [REDACTED] are 1. Right arm sprain/strain. 2. Status post right carpal tunnel release surgery on 12/12/2012. According to the report dated 07/12/2013, the patient presents with constant right wrist/hand pain. The pain is rated at 8-9/10. Examination revealed right wrist range of motion is flexion 50, extension 50, radial deviation 20, and ulnar deviation 30. The right upper extremity sensation was decreased. The patient's current medication regimen includes Norco 10/325mg, Soma 350 mg #90, Terocin compound cream, Flurbi cream, Gabacyclotram 180 g, and Somnicin. Patient was also prescribed Vicodin on 03/14/2013. The treater is requesting a refill of medications and urinalysis every 4 to 6 weeks.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**SOMA 350MG #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

**Decision rationale:** This patient presents with right arm, hand, and wrist pain. The treater is requesting a refill of Soma 350mg #90. The MTUS Guidelines page 63 regarding muscle relaxants states, "Recommended non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exasperations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility; however, in most LBP cases, they showed no benefit beyond NSAIDs and pain with overall improvement. Efficacy appears to diminish over time, and prolonged use of some medication in this class may lead to dependence." Review of medical records indicates this patient has been prescribed Soma since 04/04/2013. Muscle relaxants are recommended for short-term use only. Recommendation is for denial.

**TEROCIN 240ML: CAPSAICIN .025%-METHYL SALICYLATE 25%-MENTHOL 10%-LIDOCAINE 2.5%:** Upheld

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

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

**Decision rationale:** This patient presents with right arm, hand, and wrist pain. The treater is requesting topical compound cream, Terocin. Terocin topical cream contains capsaicin, methyl salicylate, menthol, and lidocaine. The MTUS Guidelines p 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Per MTUS, Lidocaine is only allowed in a patch form and not allowed in cream, lotion or gel forms. Recommendation is for denial.

**FLURBI (NAP) CREAM -LA 180GMS: FLURBIPROFRN 20%-LIDOCAINE5%-AMITRIPTYLINE 4%:** Upheld

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

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

**Decision rationale:** This patient presents with right arm, hand, and right wrist pain. The treater is requesting a Flurbi cream. Flurbi cream includes the ingredients flurbiprofen, lidocaine, and amitriptyline. For Flurbiprofen, MTUS states, "the efficacy in clinical trials for this treatment modality has been inconsistent, and most studies are small and of short duration. Topical NSAIDs had been shown in the meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis. Indications for use are osteoarthritis and tendinitis (in particular, that of the knee and elbow) or other joints that are amendable to topical treatment." In this case, the patient does not meet the indication for the topical medication, as he does not present with

any osteoarthritis or tendonitis symptoms. In addition, Lidocaine is only allowed in a patch form and not allowed in cream, lotion or gel forms. The MTUS Guidelines p 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Recommendation is for denial.

**GABACYCOTRAM 180GMS GABAPENTIN 10%- CYCLOBENZAPRINE 6%- TRAMADOL 10%: Upheld**

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

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

**Decision rationale:** This patient presents with right arm, hand, and wrist pain. The treater is requesting Gabacyclotram 180 g. Gabacyclotram includes gabapentin, cyclobenzaprine, and tramadol. The MTUS Guidelines regarding topical analgesics states that it is "Largely experimental in use with few randomized controlled trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Cyclobenzaprine is a muscle relaxant and is not recommended for any topical formulation. Furthermore, Gabapentin is not recommended as a topical formulation. Recommendation is for denial.

**SOMNICIN 330 CAPS: MELATONIN 2MG-5 HTP 50MG- LTRYPTOPHAN 100MG- PYRIDOXINE 10MG- MAGNESIUM 50MG: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MD Consult Drug Monograph (last updated 11/26/11) Melatonin (5-methoxy-N-acetyltryptamine).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Vitamin B, 5-Hydroxytryptophan, Melatonin and <http://sales.advancedrxmgt.com/salescontent/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>.

**Decision rationale:** This patient presents with right arm, hand, and wrist pain. The treater is requesting Somnicin. The MTUS, ACOEM and ODG guidelines do not discuss Somnicin. The search on the web indicates, "Somnicin is an oral medication of natural ingredients, helps and promotes sleep." Active Ingredients are Melatonin 2 mg, 5-HTP (5-hydroxytryptopan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg. (<http://sales.advancedrxmgt.com/salescontent/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>). Somnicin is a supplement and it is not FDA approved to treat any medical condition and cannot be considered a medical treatment for any condition. It does not fit the Labor Code 4610.5(2) definition of medical necessity. ""Medically necessary" and "medical necessity"

meaning medical treatment that is reasonably required to cure or relieve the injured employee of the effects of his or her injury..." ODG guidelines do address some of these items separately, and do not recommend melatonin-receptor agonist for more than 7-10 days, do not recommend Vitamin B supplements and 5-hydroxytryptophan is recommend for use with caution. Given that some of the ingredients lack guidelines support, recommendation is for denial.

**URINALYSIS EVERY 4-6 WEEKS:** 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), Urine Drug Screen

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Urine Drug Screen

**Decision rationale:** This patient presents with right arm, hand, and wrist pain. The treater is requesting a Urinalysis every 4-6 weeks. Medical records indicate the patient has had monthly Urine Drug Screens from February to June of 2013. Multiple tests were not consistent with the medications prescribed. While MTUS Guidelines do not specifically address how frequent UDS should be obtained for various risks of opiate users, ODG Guidelines provide clearer recommendation. It recommends 2 to 3 times a year urine screen for inappropriate or unexplained results in moderate risk patients. The patient has had three inconsistent results in the recent past. The treater does not discuss in his reports what was to be done about the inconsistent result. Instead, the treater continues to obtain monthly UDS. Without the treater's discussion regarding the UDS findings, and chronic opiate risk assessment, on going monthly UDS are not indicated. Two to three UDS per year should be sufficient to manage the patient's opiate use in most cases as per ODG guidelines. Recommendation is for denial.