

<b>Case Number:</b>	CM14-0067944		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	02/09/2010
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	04/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/12/2014

### 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 Internal Medicine 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:

This patient is a 42-year-old male who sustained a work related injury on 02/09/10 while pulling a pallet jack. In an agreed medical examination dated 11/26/13, it was mentioned that the patient underwent a trial of spinal cord stimulator on 04/06/13. A CT Scan of the lumbar spine without contrast was performed on 05/09/13 which showed previous lumbar left hemilaminectomy and discectomy and fusion L4-5 with orthopedic hardware remaining. On 09/05/13, the patient was noted to be on Norco, Ambien, and omeprazole. In a progress report dated 01/17/14, it was noted that the patient was stable on his current medication regimen of four Norco per day and Ambien for insomnia. He reported that symptoms were not worsening and there were no side effects noted. It was noted that the patient continued to have insomnia. Physical examination revealed that the patient was awake, alert, and not in acute distress. The patient was diagnosed with depressive disorder, radiculopathy in the left lower extremity, lumbar myoligamentous injury, status post L4-5 discectomy on 03/03/11. He was advised to continue with conservative care utilizing maintenance of Hydrocodone at four per day with Ambien for severe insomnia, continue with H-wave utilization, continue with transdermal analgesic ointments, and continue with self-physiotherapeutic exercises.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Flurbiprofen/Lidocaine/Amitriptyline (duration and frequency unknown) for treatment of lumbar spine dispensed on 01/20/2014: 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 111-113 NSAIDs, specific drug list & adverse effects Page 70 Page(s): 111-113, 70. Decision based on Non-MTUS Citation Mayo Clinic Proceedings: Topical Analgesics in the Management of Acute and Chronic Pain, Volume 88, Issue 2, pages 195-205, February 2013.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Besides Lidoderm, no other commercially approved topical formulation of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend topical Lidocaine for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical Lidocaine is not recommended for non-neuropathic pain. There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). Use of NSAIDs may compromise renal function. FDA medication guide recommends lab monitoring of a CBC and chemistry profile (including liver and renal function tests). Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Mayo Clinic Proceedings article titled Topical Analgesics in the Management of Acute and Chronic Pain (2013) describes the results of a systematic review of the efficacy of topical analgesics in the management of acute and chronic pain conditions, including topical Amitriptyline, and concluded that limited evidence is available to support the use of topical Amitriptyline in acute and chronic pain. Medical records do not document blood pressure measurements or laboratory test results, which are recommended by MTUS for the use of NSAIDs. Medical records do not document a diagnosis of post-herpetic neuralgia, which is the only indication for topical Lidocaine. Mayo Clinic Proceedings do not support the use of topical Amitriptyline. Per MTUS, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for Flurbiprofen/Lidocaine/Amitriptyline (duration and frequency unknown) for treatment of lumbar spine DOS: 01/20/2014 is not medically necessary.

**Retrospective Somnicin (duration and frequency unknown) dispensed on 01/20/2014:**  
Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine Official Disability Guidelines (ODG).

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

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) does not address Somnicin. Somnicin is labeled as a dietary supplement sleep aid. Official Disability Guidelines (ODG) states that "regarding insomnia treatment, after a few weeks, the recommendation is to discontinue the medication. Patients do better in the long term if medication is stopped after 6 weeks." Medical records document the long-term use of medication for insomnia. Long-term use of medication for insomnia is not supported by ODG guidelines. Per ODG, Vitamin B is not recommended. ODG Guidelines classifies 5-hydroxytryptophan as a medical food. Per ODG, a medical food must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. No distinctive nutritional requirements were documented in the medical records. There are no randomized controlled trials that support the effectiveness of Somnicin. The use of Somnicin is not supported by clinical practice guidelines or medical literature. Therefore, the request for Somnicin (duration and frequency unknown) DOS: 01/20/2014 is not medically necessary.

**Retrospective Gabapentin/Cyclobenzaprine/Tramadol (duration and frequency unknown) for treatment of lumbar spine dispensed on 01/20/2014:** 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): 111-113.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. There is no evidence for use of a muscle relaxant as a topical product. Gabapentin is not recommended. There is no peer-reviewed literature to support use. There is no evidence for use of any other antiepilepsy drug as a topical product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS guidelines do not support the use of topical product containing Gabapentin and Cyclobenzaprine. Therefore, the request for retrospective Gabapentin/ Cyclobenzaprine/Tramadol (duration and frequency unknown) for treatment of lumbar spine DOS: 01/20/2014 is not medically necessary.