

<b>Case Number:</b>	CM15-0024477		
<b>Date Assigned:</b>	02/17/2015	<b>Date of Injury:</b>	12/24/2011
<b>Decision Date:</b>	04/01/2015	<b>UR Denial Date:</b>	01/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/09/2015

### 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: New York  
 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:

This is a 58 year-old female who has reported multifocal pain after falling on 12/24/11. The diagnoses include lumbago, radiculopathy, anterior cruciate ligament and meniscal tears, rib fractures, and complex regional pain syndrome. Treatment has included knee surgery, a spinal cord stimulator, physical therapy, and medications. The records refer to a successful spinal cord stimulator trial on 7/9/14 preceded by an internal medicine evaluation earlier in 2014. The records show that the injured worker was requesting permanent implantation of the unit and that this was planned prior to the injured worker seeing the current primary treating physician. The records state that the injured worker never returned to work after the injury in 2011. The current treating physician first saw this injured worker on 11/17/14. He noted the prior spinal cord stimulator trial with temporary pain relief. Ongoing medications included Ambien, gabapentin, hydrocodone, and naproxen. There was no discussion of the specific results of using these medications. A specific sleep disorder was not described. Documentation included a psychological evaluation dated 9/17/2014. Ambien, gabapentin, ibuprofen, and Norco were prescribed. There was no work status documented. Per the PR2 dated 11/16/15, there was ongoing low back and knee pain. The physical findings consisted of decreased range of motion measurement. The diagnoses were lumbago and radiculopathy. The treatment plan included a spinal cord stimulator trial, psychological evaluation, and the medications listed in this review. The specific indications for the medications were not mentioned or discussed. On 1/26/15 Utilization Review non-certified the evaluations and medications now under Independent Medical Review. Utilization Review certified gabapentin, ibuprofen, oxycodone, Genicin,

glucosamine, and a neurostimulator for the lumbar spine. The MTUS and the Official Disability Guidelines were cited.

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

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

**Psychosocial evaluation (psychological clearance prior to undergoing SCS trial): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Psychological evaluations, IDDS & SCS (intrathecal drug delivery systems & spinal cord stimulators) Page(s): 101.

**Decision rationale:** Although psychological evaluations are recommended prior to spinal cord stimulator implantation, this injured worker has already had psychological evaluation and psychological treatment followed by a successful spinal cord stimulator trial. There were already plans in place to permanently implant a spinal cord stimulator. There is therefore no medical necessity to start the process over again with further evaluations or another trial.

**Evaluation with specialist (internal medicine surgical clearance evaluation with routine laboratory work up): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Spinal cord stimulators (SCS) Page(s): 106.

**Decision rationale:** This injured worker has already had an internal medicine evaluation followed by a successful spinal cord stimulator trial. There were already plans in place to permanently implant a spinal cord stimulator. There is therefore no medical necessity to start the process over again with further evaluations or another trial. In addition, the treating physician has not discussed any specific indications or medical conditions for which a repeat evaluation might be necessary.

**Ambien 10 mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The MTUS does not address the use of hypnotics other than benzodiazepines. The Official Disability Guidelines were used instead. The Official Disability Guidelines recommend the short term use of hypnotics like zolpidem (less than two months), discuss the significant side effects, and note the need for a careful evaluation of the sleep difficulties. No physician reports describe the specific criteria for a sleep disorder. The treating physician has not addressed other major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep architecture. The results of using zolpidem were not discussed. Zolpidem, a benzodiazepine agonist, is habituating and recommended for short term use only. This injured worker has been given a hypnotic for a duration in excess of what is recommended in the guidelines cited above. Note the ODG citation which recommends short term use of zolpidem, a careful analysis of the sleep disorder, and caution against using zolpidem in the elderly. Prescribing in this case meets none of the guideline recommendations. Zolpidem is not medically necessary based on lack of a sufficient analysis of the patient's condition, the ODG citation, and overuse of habituating and psychoactive medications without clear benefit or indication.

**Terocin 120 ml: Capsaicin 0.025%, Menthol Salicylate 25%, Menthol 10%, Lidocaine 2.5%:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain; Topical Analgesics Page(s): 60; 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: December 5, 2006 FDA Alert, FDA Warns Five Firms To Stop Compounding Topical Anesthetic Creams.

**Decision rationale:** The treating physician has not discussed the ingredients of Terocin and the specific indications for this injured worker. Per the manufacturer, Terocin is Methyl Salicylate 25%, Menthol 10%, Capsaicin 0.025%, Lidocaine 2.5%, Aloe, Borage Oil, Boswellia Serrata, and other inactive ingredients. Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of any specific medication contraindications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Boswellia serrata resin and topical lidocaine other than Lidoderm are "not recommended" per the MTUS. Note the FDA warning cited above. Topical lidocaine like that in Terocin is not indicated per the FDA, and places patients at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin alone in the standard formulation readily available OTC may be indicated for some patients. The indication in this case is unknown, as the patient has not failed adequate trials of other treatments. Capsaicin is also available OTC, and the reason for compounding the formula you have prescribed is not clear. Terocin is not medically necessary based on lack of specific medical indications, the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

**Flurbi (NAP) cream-LA 180 gms: Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4%:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain; Topical Analgesics Page(s): 60; 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: December 5, 2006 FDA Alert, FDA Warns Five Firms To Stop Compounding Topical Anesthetic Creams.

**Decision rationale:** Per page 60 of the MTUS, medications should be trialed one at a time. Regardless of any specific medication contraindications for this patient, the MTUS recommends against starting 3-7 medications simultaneously. Per the MTUS, any compounded product that contains at least one drug that is not recommended, is not recommended. Topical lidocaine other than Lidoderm is "not recommended" per the MTUS. Note the FDA warning above. Topical anesthetics like the ones dispensed are not indicated per the FDA, are not FDA approved, and place injured workers at an unacceptable risk of seizures, irregular heartbeats and death. In addition, the treating physician has dispensed two topical forms of lidocaine, which increases the toxicity. There is no good evidence to support topical amitriptyline. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. This injured worker is already taking an oral NSAID, making a topical NSAID duplicative and unnecessary, as well as possibly toxic. The topical agents prescribed are not medically necessary based on the MTUS, lack of medical evidence, FDA directives, and inappropriate prescribing.

**Gabaclotram 180 gms: Gabapentin 10%, Cyclobenzaprine 5%, Tramadol 10%:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain; Topical Analgesics Page(s): 60; 111-113.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical gabapentin and cyclobenzaprine are not recommended per the MTUS. There is no good evidence to support topical tramadol. The topical agents prescribed are not medically necessary based on the MTUS, lack of medical evidence, and inappropriate prescribing.

**Somnicin #30: Melatonin 2 mg-5HTP 50 mg- L tryptophan 100 mg-Pyridixine 10 mg-Magnesium 50 mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Insomnia treatment, melatonin, vitamin B and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: ACOEM Guidelines, Chronic Pain update, 2008, page 137: Vitamins for Chronic Low Back and Other Chronic Pain.

**Decision rationale:** Somnicin contains melatonin, 5-HTP, L-tryptophan, vitamin B6, and magnesium. The MTUS does not provide direction for the use of vitamins, minerals, or hypnotics other than benzodiazepines. The treating physician has not discussed these ingredients and their specific indications for this injured worker. There was no evidence of any specific nutritional deficiencies for which an amino acid, vitamin, or mineral would be indicated. Melatonin alone may have indications for some medical conditions, including certain kinds of sleep disorders, per the Official Disability Guidelines citation above. The treating physician has not described any of these conditions. The treating physician has provided no evidence of a vitamin deficiency or any other specific indication for vitamin replacement. The Official Disability Guidelines citation above recommends against vitamin B for chronic pain. The ACOEM update cited above recommends against vitamin supplementation unless there is a documented deficiency, which there is not in this case. There is no medical necessity for Somnicin based on the guidelines and the available records.