

<b>Case Number:</b>	CM14-0050064		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	08/26/2011
<b>Decision Date:</b>	09/09/2014	<b>UR Denial Date:</b>	03/13/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/17/2014

### 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 Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine, and is licensed to practice in Texas and Oklahoma. 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 injured worker is a 50-year-old female who reported an injury on 8/26/11. The mechanism of injury was cumulative trauma. The injured worker's diagnoses included degenerative disc disease of the lumbar spine, lumbar spine facet syndrome, and chronic pain. Past treatment history includes drug therapy, activity modification, and physical therapy. The injured worker's diagnostics were EMG/NCV performed on 8/22/13. The injured worker's surgical history included a left knee surgery on 8/26/11 and a laparoscopy 15 years ago, and two left knee surgeries and carpal tunnel release dated 7/30/13. The injured worker complained of constant severe low back pain that radiates to the bilateral lower extremities with difficulty walking. On physical examination dated 12/17/13 there was tenderness to palpation of the lumbar paravertebral and decreased range of motion to the lumbar spine. The provider's treatment plan was for the injured worker to continue pain medications, home exercises, and awaiting authorization for a lumbar epidural steroid injection.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**New Terocin:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topicals Page(s): 143.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topicals Analgesics Page(s): 111. Decision based on Non-MTUS Citation <http://en.wikipedia.org/wiki/Menthol>.

**Decision rationale:** The injured worker's chief complaint was persistent low back pain. According to the California MTUS, topical analgesics are 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 a lack of systemic side effects, absence of drug interaction, and no need to titrate. Lidocaine is indicated for neuropathic pain and is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy like a tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica. Topical lidocaine, in the formulation of a dermal patch called Lidoderm has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. Menthol has local anesthetics and counterirritants qualities, and it is widely used to relieve minor throat irritation. Menthol also acts as an opioid agonist. There is documentation of a failed conservative treatment of drug therapy and physical therapy. There is no documentation submitted of a failed trial of antidepressants or anticonvulsants. In the absence of documentation of a failed antidepressant or anticonvulsant trial, the evidence based guidelines do not support the request. Additionally, the request failed to include a dosage and a frequency of the medication. As such, the request is not medically necessary.

**Flurbiprofen/Lidocaine/Amitriptyline:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topicals Page(s): 143.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**Decision rationale:** According to the California MTUS Guidelines, they state topical analgesics are largely experimental in use with few randomized controlled trials to determine the efficacy or safety of the medication. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is no documentation of neuropathic pain on physical examination, as well as no documentation of failed trials of antidepressants or anticonvulsants. Guidelines states that Lidocaine is indicated for neuropathic pain and is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy of an antidepressant or antiepileptic drug such as gabapentin or Lyrica. Topical lidocaine, in the formulation of a dermal patch Lidoderm has been designated for orphan status by the FDA for neuropathic pain. There is also lack of a more current clinical examination for subjective and objective information. In addition, the frequency and the area of the body of the medication to be applied were not provided in the request that was submitted. As such, the request is not medically necessary.

**Gabapentin/Cyclobenzaprine/Tramadol:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topicals Page(s): 143.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic Page(s): 63, 111, 113.

**Decision rationale:** The California MTUS Guidelines state that topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety. The guidelines also state that, if any compounded product contains at least 1 drug or 1 drug class that is not recommended, then the whole compound is not recommended. The topical analgesic request that was submitted for review contains Gabapentin and, per guidelines, Gabapentin is not recommended in topical formulation due to there is no peer reviewed literature to support use. The requested medication also contains cyclobenzaprine, which is classified as a muscle relaxant, and muscle relaxants are not recommended for topical use. In addition, there is no frequency or body location listed on the current request. As such, the request is not medically necessary.

**Somnicin:** Upheld

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

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

**Decision rationale:** According to the Official Disability Guidelines, Melatonin is recommended treatment for insomnia. There are also experimental and clinical data supporting an analgesic role of melatonin. In published studies melatonin shows potent analgesic effects in a dose-dependent manner, and melatonin has been shown to have analgesic benefits in patients with chronic pain. Also, the repeated administration of melatonin improves sleep and thereby may reduce anxiety, which leads to lower levels of pain. The injured worker is complaining of constant low back pain and the duration period of treatment is not known, but most double blind trials have been of short duration, 6 weeks to 12 weeks. The efficacy of the medication was not provided for review to support continuation. The request submitted for review failed to include the frequency and the dosage of the medication. As such, the request for Somnicin is not medically necessary.