

<b>Case Number:</b>	CM14-0029037		
<b>Date Assigned:</b>	04/09/2014	<b>Date of Injury:</b>	11/05/2012
<b>Decision Date:</b>	05/13/2014	<b>UR Denial Date:</b>	01/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/21/2014

### 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 Ohio. 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 24-year-old male who reported an injury on 11/05/2012. The mechanism of injury was that the injured worker was trying to move a ladder from one side of his body to the other and felt a pop. The documentation of 10/18/2013 revealed that the injured worker had complaints of constant pain in the low back traveling to both legs, which he described as numbness, tingling, cramps and needles. The injured worker rated the pain at a 6/10. The injured worker complained of his thigh, foot and toe being cold, and he had associated complaints of numbness and tingling. It was indicated that the injured worker took pain medications, and the pain level of 6/10 was with medications. The injured worker indicated that the pain was reduced with rest, activity modification, heat and cold as well as physiotherapy and chiropractic treatment. The diagnoses were a lumbar disc bulge; spasm of muscle; unspecified sleep disturbance; and anxiety, stated unspecified. The request was made for continued chiropractic treatment, traction and electrical stimulation as well as a lumbar exercise kit, a transcutaneous electrical nerve stimulation unit, a positional weight bearing MRI (magnetic resonance imaging) and an orthopedic surgery consultation to address the lumbar spine.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**TEROCIN 240ML (CAPSAICIN 0.025%, METHYL SALICYLATE 25%, MENTHOL 10%, LIDOCAINE 2.5%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate; Topical Analgesic; Topical Capsaicin; Section Lidocaine Page(s): 105; 111; 2. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Terocin>

**Decision rationale:** The California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. MUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. For capsaicin, it is recommended only as an option in patients who have not responded or are intolerant to other treatments. For Lidocaine/Lidoderm: no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The California MTUS Guidelines recommend treatment with topical salicylate. Per Drugs.com, Terocin is a topical analgesic containing capsaicin/lidocaine/menthol/ methyl salicylate. The clinical documentation submitted for review failed to indicate that the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the medication. No duration could be established with the submitted records. [REDACTED]

[REDACTED] Given the above and the lack of documentation, the request for Terocin 240 mL (capsaicin 0.025%, methyl salicylate 25%, menthol 10%, lidocaine 2.5%) is not medically necessary.

**FLURBI (NAP) CREAM- LA 180GMS (FLURBIPROFEN 20%, LIDOCAINE 5%, AMITRIPTYLINE 4%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Flurbiprofen; Lidocaine; Antidepressants Page(s): 111, 72, 112, 113. Decision based on Non-MTUS Citation Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use 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. Topical nonsteroidal anti-inflammatory drugs (NSAIDs) have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. This agent is not currently Food and Drug Administration (FDA) approved for a topical application. The FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. Regarding the use of Lidocaine/Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams,

lotions or gels) are indicated for neuropathic pain. Peer reviewed literature states that while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of N-Methyl-D-aspartate (NMDA), nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined. The clinical documentation submitted for review failed to indicate that the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the medication. No duration could be established with the submitted records. [REDACTED]

[REDACTED] Given the above and the lack of documentation, the request for flurbi (NAP) cream - LA 180 gm (flurbiprofen 20%, lidocaine 5%, amitriptyline 4%) is not medically necessary.

**GABACYCLOTRAM 180MGS (GABAPENTIN 10%, CYCLOBENZAPRINE 6%, TRAMADOL 10%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; Topical Analgesics; Gabapentin; Tramadol. Decision based on Non-MTUS Citation FDA.gov

**Decision rationale:** The CA MTUS states that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product. The guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy per CA MTUS Guidelines. The clinical documentation submitted for review failed to indicate that the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the medication. No duration could be established with the submitted records.

[REDACTED] Given the above and the lack of documentation, the request for gabacyclotram 180 gms (gabapentin 10%, cyclobenzaprine 6%, tramadol 10%) is not medically necessary.

**GENICIN #90 CAPS:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

**Decision rationale:** The California MTUS Guidelines recommend glucosamine for the treatment of osteoarthritis. There was a lack of documentation indicating that the injured worker had osteoarthritis. The request as submitted failed to provide the frequency for the medication. No duration could be established with the submitted records. [REDACTED]

[REDACTED] Given the above, the request for Genicin #90 caps is not medically necessary.

**SOMNICIN #30 CAPS:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES PAIN CHAPTER: MELATONIN. NON-MTUS

**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, and Other Medical Treatment Guideline or Medical Evidence: <http://sales.advancedrxmgmt.com/sales-content/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>

**Decision rationale:** The Official Disability Guidelines (ODG) indicates that non-pharmacologic treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention. The treatments that are thought to probably be efficacious include sleep restriction, biofeedback, and multifaceted cognitive behavioral therapy. Suggestions for improved sleep hygiene: (a) Wake at the same time every day; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. Per advancedrxmgmt.com, "Somnicin, an oral medication of natural ingredients, helps and promotes sleep. Insomnia and sleeping problems can be linked to pain and often thought of as a sign and/or symptom of physical, emotional, and/or mental health. Somnicin's ingredients help relax the body, allow adequate blood flow, and may help in other conditions such as depression, anxiety, or some pains. Melatonin, 5-HTP, and L-tryptophan, help balance the pathway responsible for a normal sleep cycle". Also included in the compound are B-6 and Magnesium. The clinical documentation submitted for review failed to indicate the signs and symptoms of the injured worker's unspecified sleep disturbance. [REDACTED]

[REDACTED] No duration could be established with the submitted

records. The frequency was not provided. Given the above, the request for Somnicin #30 caps is not medically necessary.