

<b>Case Number:</b>	CM14-0080121		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	10/31/2013
<b>Decision Date:</b>	09/18/2014	<b>UR Denial Date:</b>	05/10/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/30/2014

### 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 Orthopedic Surgery and is licensed to practice in Texas. 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 34-year-old female who reported injury on 10/31/2013. The mechanism of injury was repetitive trauma. Her medication history included Terocin lotion, Flurbi (NAP) cream, Gabacyclotram, Genicin, GABADone, Theramine, Sentra AM and PM, and opioids as of 12/2013. The diagnostic studies and were not provided. The surgical history included left wrist carpal tunnel release. The most recent documentation was dated 04/17/2014 which revealed the injured worker had complaints of constant wrist pain radiating to the fingers with numbness and tingling. She indicated she had no GI symptoms with the use of medications including oral and topical medications. Her pain without medications was noted to be 9/10 and with medications 3/10. The objective findings revealed she had a positive Phalen's and Tinel's bilaterally. The diagnosis was left wrist status post-surgery 02/04/2014, right wrist carpal tunnel syndrome. The treatment plan included Norco 10/325 mg #45, a qualitative drug screen, an orthopedic evaluation for the right wrist, and a non-contrast MRI of the right wrist. There was no request for authorization or physician progress report for the requested medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain, Ongoing Management Page(s): 60, 78.

**Decision rationale:** The California MTUS Guidelines recommend opioids for the treatment of chronic pain. There should be documentation of objective functional improvement, objective decrease in pain and documentation the injured worker is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review indicated the injured worker was being monitored for aberrant drug behavior and side effects and had an objective decrease in pain. There was, however, a lack of documentation of objective functional benefit. The documentation indicated the injured worker had utilized the medication since at least 12/2013. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Norco 10/325 mg #30 is not medically necessary.

**Genicin #90:** Upheld

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

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

**Decision rationale:** The California MTUS Guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. The clinical documentation submitted for review indicated the injured worker had utilized the medication since 12/2013. However, there was a lack of documented efficacy and there was a lack of documentation indicating the injured worker had moderate arthritis pain or findings of arthritis. The objective functional benefit was not provided. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Genicin #90 is not medically necessary.

**Somnicin #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 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 indicates that non-pharmacologic treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention and is a first line treatment for insomnia. Per [advancedrxmgmt.com](http://advancedrxmgmt.com), the ingredients include Melatonin, 5-HTP, L-tryptophan, compound B-6 and Magnesium. Additionally, the Official Disability Guidelines, Melatonin is recommended in the treatment of sleep disorders. A thorough search of the California MTUS, Official Disability Guidelines, and the National Guideline

Clearinghouse failed to reveal guidelines or scientific evidence to L-tryptophan, Pyridoxine, or Magnesium in the management of insomnia. The clinical documentation submitted for review indicated the injured worker had utilized the non-pharmacological treatment. However, there was a lack of documentation indicating objective functional improvement. There was a lack of documentation of the duration of use in the supplied documentation. The request as submitted failed to indicate the frequency for the requested Somnicin. Given the above, the request for Somnicin #30 is not medically necessary.

**Terocin lotion:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines Salicylate Topicals, Topical Analgesic,, Topical Capsaicin,Lidocaine Page(s): 105, 111, 28, 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Terocin>.

**Decision rationale:** The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety, 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. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. The guidelines indicate that topical Lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per Drugs.com, Terocin is a topical analgesic containing Capsaicin / Lidocaine / Menthol / Methyl Salicylate. There was a lack of documentation indicating the injured worker had a trial and failure of anticonvulsants and antidepressants. The clinical documentation submitted for review indicated the injured worker had utilized the topical medication since at least 12/2013. There was a lack of objective functional benefit and an objective decrease in pain. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the quantity, frequency and strength for the requested medication. Given the above, the request for Terocin lotion is not medically necessary.

**Flurbi (NAP) cream LA:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines Flurbiprofen, Topical analgesics Lidocaine Antidepressants Page(s): 72, 111, 112, 13.

Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Skolnick P (1999) Antidepressants for the new millennium.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The guidelines indicate that topical Lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as Gabapentin or Lyrica). No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Per Skolnick, P. (1999) "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 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 documentation indicated the injured worker had utilized the medication since at least 12/2013. There was a lack of documented objective functional benefit and an objective decrease in pain. The request as submitted failed to indicate the frequency, quantity and strength for the requested medication. Given the above, the request for Flurbi (NAP) is not medically necessary.

**Gabacyclotram cream:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics, Gabapentin, Tramadol Page(s): 41, 111, 113, 82. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA.gov.

**Decision rationale:** The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety... 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 is 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 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. Additionally, per California MTUS, the approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. The duration of use was since at least 12/2013. There was a lack of documented efficacy and objective functional benefit. The request as submitted failed to indicate the frequency, quantity and strength for the requested medication. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for Gabacyclotram cream is not medically necessary.