

<b>Case Number:</b>	CM13-0042555		
<b>Date Assigned:</b>	12/27/2013	<b>Date of Injury:</b>	12/17/2012
<b>Decision Date:</b>	02/20/2014	<b>UR Denial Date:</b>	10/14/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/19/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Ohio and 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 physician 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 patient is a 40-year-old male who reported injury on 12/17/2012. The mechanism of injury was stated to be the patient slipped while pushing a dolly full of product and caught himself on the ground with his outstretched right hand. The patient was noted to have right shoulder pain radiating up to the neck. The examination of the right shoulder was noted to indicate the patient had tenderness and limited range of motion. The patient's diagnosis was noted to be right shoulder sprain/strain. The treatment plan was noted to include a refill of Genicin and Somnicin, and to include a new topical and refills of 2 other topicals.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Gabapentin/Cyclobenzaprine/Tramadol prescribed 6/5/2013 for the right shoulder: Upheld**

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

**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 FDA.gov

**Decision rationale:** CA MTUS indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety...Any compounded product that contains at least 1 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...do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant 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 CA MTUS, the approved form of tramadol is for oral consumption, which is not recommended as a first line therapy. The clinical documentation submitted for review failed to provide the necessity for the requested medication. Additionally, there was a lack of documentation indicating the quantity of medication being requested, and there was a lack of documentation of exceptional factors to warrant nonadherence to guideline and FDA indications. Given the above, the request for Gabapentin/Cyclobenzaprine/Tramadol prescribed 6/5/13 for the right shoulder is not medically necessary.

**Somnicin:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 9th Edition (web), 2011, Pain, Compounded Drugs

**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 Treatments and the online advancedrxmgmt.com.

**Decision rationale:** 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." Official Disability Guidelines recommend non-pharmacologic treatment, including stimulus control, progression muscle relaxation, and paradoxical intention. There is a lack of documentation indicating the efficacy of the requested medication. Additionally, there is a lack of documentation indicating if the patient has tried non-pharmacologic interventions. There is a lack of documentation indicating the quantity or strength of Somnicin. Given the above and the lack of submitted documentation, the request for Somnicin is not medically necessary.

**Genicin:** Upheld

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

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

**Decision rationale:** California MTUS Guidelines recommend glucosamine in patients with moderate arthritis pain, especially for knee osteoarthritis. The clinical documentation submitted for review failed to provide the patient had documented knee osteoarthritis. It failed to provide documentation of the efficacy of the requested medication. Additionally, it failed to provide the quantity and strength being requested. Given the above and the lack of documentation, the request for Genicin is not medically necessary.

**Terocin:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate , Topical Analgesic, Capsaicin, Lidocaine, Page(s): 105,111,112. Decision based on Non-MTUS Citation the web online drugs.com.

**Decision rationale:** CA MTUS indicates that topical analgesics are "Largely experimental in use with few randomized control trials to determine efficacy or safety...Any compounded product that contains at least 1 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...Lidocaine... Lidoderm...No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." California MTUS Guidelines recommend treatment with topical salicylates. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. Additionally, there was a lack of documentation indicating the patient had not responded or was intolerant to other treatments. There is a lack of documentation indicating the necessity for 2 products containing lidocaine, as the medication is being concurrently reviewed with another topical compound that contains lidocaine. There is a lack of documentation indicating the quantity of Terocin being requested. Given the above, the request for Terocin is not medically necessary.

**Flurbiprofen/Lidocaine/Amitriptyline:** Upheld

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

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

**Decision rationale:** Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. The CA MTUS indicates topical analgesics are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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." This agent 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...Lidocaine...Lidoderm...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 clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. Additionally, there is a lack of documentation indicating the necessity for 2 compounds with the same medication of lidocaine. There is a lack of documentation indicating the quantity of medication being requested. Given the above, the request for Flurbiprofen/Lidocaine/Amitriptyline is not medically necessary.