

<b>Case Number:</b>	CM15-0076279		
<b>Date Assigned:</b>	04/28/2015	<b>Date of Injury:</b>	10/05/2005
<b>Decision Date:</b>	08/04/2015	<b>UR Denial Date:</b>	03/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/21/2015

### 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: Internal 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:

The injured worker is a 62 year old female, who sustained an industrial/work injury on 10/5/05. She reported initial complaints of right shoulder and wrist pain. The injured worker was diagnosed as having bilateral shoulder internal derangement and s/p bilateral wrist surgery. Treatment to date has included medication and injection. Currently, the injured worker complains of constant right shoulder pain, 7/10 and constant bilateral wrist pain with numbness and tingling, rated 5-6/10. Per the primary physician's progress report (PR-2) on 3/18/15, examination revealed tenderness along the acromioclavicular joint bilaterally and along the trapezius muscles bilaterally with spasms, decreased sensation to light touch along the C6-C7 nerve root distribution along the right upper extremity. The requested treatments include Omeprazole, Calypso cream, Terocin pain patch, Norco, Terocin, Flurbi cream, Gabaclyotram, Genicin, and Somnicin.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Omeprazole 20mg #60:** 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 Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--Proton pump inhibitors (PPIs).

**Decision rationale:** According to CA MTUS (2009), proton pump inhibitors, such as Omeprazole are recommended for patients at risk for gastrointestinal events or taking NSAIDs with documented GI distress symptoms. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. There is no documentation of any reported GI complaint in this injured worker. Based on the available information provided for review, the request is not medically necessary.

**Calypoxo cream 118gm:** 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 Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least one non-recommended drug (or drug class) is not recommended for use. Based on the currently available medical information for review, there is no documentation about the composition, of this cream and why this particular cream is requested, the request is not medically necessary.

**Terocin pain patch #20:** 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 Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example,

NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous medications. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

**Norco 5/325mg #90:** 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 Opioids Page(s): 91-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--Opioids.

**Decision rationale:** According to the CA MTUS and ODG, Norco 10/325mg (Hydrocodone/Acetaminophen) is a short-acting opioid analgesic indicated for moderate to moderately severe pain, and is used to manage both acute and chronic pain. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's pain relief effectiveness, functional improvement from previous usage, or response to ongoing opiate therapy. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Terocin 120ml:** 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 Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no

documentation of intolerance to other previous medications. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

**Flurbi cream 180gms:** 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 Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least one non-recommended drug (or drug class) is not recommended for use. Flurbiprofen is used as a topical NSAID. It has been shown in a meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis but either, not afterward, or with diminishing effect over another two-week period. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). Records do not indicate that injured worker is not able to use oral medications. There is no documentation in the submitted Medical Records that the injured worker has failed a trial of antidepressants and anticonvulsants. Dose, and frequency has not been specified. In this injured worker, the medical necessity for the requested topical cream has not been established. Therefore, as per guidelines stated above, the requested topical cream is not medically necessary.

**Gabaclyotram 180gms:** 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 Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Gabaclyotram. One of the ingredients of Gabaclyotram is gabapentin. MTUS states that gabapentin is not recommended topically. There

is no peer-reviewed literature to support use. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

**Genicin #90:** 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 - Chondroitin/Glucosamine.

**Decision rationale:** As per ODG Criteria it is Recommended as an option (glucosamine sulfate only) given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). For all herbals and dietary supplements, there may be concerns for potential interactions with prescription and over-the-counter medications and lack of manufacturing quality controls. In this case, there is no compelling evidence presented by the treating provider that indicates this injured worker has had any significant improvements from this medication, and also review of Medical Records do not clarify that previous use of this medication has been effective in this injured worker for maintaining any functional improvement. The requested medication 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.

**Decision rationale:** The prescription for Somnicin is evaluated in light of Official Disability Guidelines (ODG) recommendations for Insomnia treatment. ODG recommend that treatment be based on the etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Non-pharmacologic treatment: Empirically supported treatment includes stimulus control, progressive muscle relaxation, and paradoxical intention. Treatments that are thought to probably be efficacious include sleep restriction, biofeedback, and multifaceted cognitive behavioral therapy. Somnicin is a combination of melatonin, magnesium oxide, tryptophan add

oxitriptan. There are no evidence based guidelines for the combination components of this medicine and if one component of the medicine is not indicated, then the whole medication cannot be approved. In this case, there is no compelling evidence presented by the treating provider that indicates this injured worker has had any significant improvements from this medication, and also review of Medical Records do not clarify that previous use of this medication has been effective in this injured worker for maintaining any functional improvement. The request is not medically necessary.