

<b>Case Number:</b>	CM14-0018795		
<b>Date Assigned:</b>	04/18/2014	<b>Date of Injury:</b>	10/22/2012
<b>Decision Date:</b>	04/10/2015	<b>UR Denial Date:</b>	01/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/13/2014

### 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. 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: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 64-year-old male, who sustained an industrial injury on 10/22/12. He has reported back pain. The diagnoses have included lumbar radiculitis, left shoulder sprain/strain and left shoulder osteoarthritis. Treatment to date has included medications and back brace. Currently, the injured worker complains of constant back pain and constant left shoulder pain with numbness and tingling. Progress report dated 12/2/13 revealed limited range of motion of lumbar spine and tenderness of lumbar spine. On 1/21/14 Utilization Review non-certified Terocin 240 ml, Flurbi cream-LA 180gms, Gabacyclotram 180gms, Gabapentin 10%, noting there is no supporting evidence to use combination pain control agents and non-certified Genicin #90, noting evidence does not show benefit regarding this medication and Somnicin 2mg #30, noting there is no demonstrated nutritional deficiency demonstrated that would require the use of this compounded medication. The MTUS, ACOEM Guidelines, was cited. On 2/18/14, the injured worker submitted an application for IMR for review of Terocin 240 ml, Flurbi cream-LA 180gms, Gabacyclotram 180gms, Gabapentin 10%, Genicin #90 and Somnicin 2mg #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**TEROCIN 240ML:** 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 Topical Analgesics Page(s): 111-112 of 127.

**Decision rationale:** Terocin topical pain lotion is a topical analgesic ointment containing Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. Capsaicin may have an indication for chronic lower back pain in this context. However, the CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. Terocin topical pain lotion is a topical analgesic ointment containing Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)." However, the CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended.

**FLURBI (NAP) CREAM- LA 180GMS:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112 of 127.

**Decision rationale:** The California MTUS guidelines support topical NSAIDs for the short-term treatment of osteoarthritis and tendinitis for individuals unable to tolerate oral non-steroidal anti-inflammatories. The guidelines support 4-12 weeks of topical treatment for joints that are amendable topical treatments; however, there is little evidence to support treatment of osteoarthritis of the spine, hips or shoulders. When noting the injured employees diagnosis of low back pain with radicular symptoms and a shoulder sprain/strain and shoulder arthritis, this request for flurbiprofen cream is not medically necessary.

**GABACYCLOTRAM 180GMS:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 56, 111, 112 of 127.

**Decision rationale:** Gabacyclotram is a topical preparation that contains gabapentin, cyclobenzaprine, and tramadol. The MTUS notes that the use of topical medications are largely experimental and there have been few randomized controlled trials. It further goes on to note that topical muscle relaxers and gabapentin are not recommended clinically indicated. There is also no known efficacy for topical usage of tramadol. As this compound contains all of these medications, this request is considered not medically necessary.

**GENICIN (GLUCOSAMINE SODIUM 500MG), #90:** Upheld

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

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

**Decision rationale:** The official disability guidelines indicates that glucosamine is not indicated for the treatment of low back pain. Glucosamine has been shown not to be significantly different from placebo in reducing pain related disability or improving quality of life in individuals with chronic low back pain. It is also not recommended for shoulder disorders. Considering the injured employee symptoms and diagnoses as well as the guideline recommendations, this request for Genicin is not medically necessary.

**GABAPENTIN 10%:** 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 Topical Analgesics Page(s): 113 of 127.

**Decision rationale:** MTUS Chronic Pain Guidelines state that topical analgesics are "largely experimental" and that "any compound product that contains at least one drug (or drug class) that is not recommended, is not recommended". Additionally, the guidelines state there is no evidence to support the use of topical gabapentin and recommend against the addition of Gabapentin to other agents. Therefore, this request is not considered medically necessary.

**SOMNICIN 2MG, #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES (ODG)- MEDICAL FOODS.

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

**Decision rationale:** Somnicin is a topical compound of magnesium oxide, melatonin, oxitriptan and tryptophan. Melatonin is recommended as an option for sleep disorder post-TBI. There is no other known benefit for the injured employees condition with the usage of magnesium oxide, oxycodone 10, and tryptophan. Additionally, per the California MTUS guidelines when one ingredient of a compound is not certified the entire compound is not certified. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. As such, this request for Somnicin is not medically necessary.