

<b>Case Number:</b>	CM15-0137447		
<b>Date Assigned:</b>	07/29/2015	<b>Date of Injury:</b>	10/20/2010
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	06/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/15/2015

### 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: Arizona, Michigan

Certification(s)/Specialty: Preventive Medicine, Occupational 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 53 year old male who sustained an industrial injury on 10/20/2010. The mechanism of injury was not provided. Treatment provided to date has included: medications; and conservative therapies/care. Diagnostic tests performed include: MRI of the lumbar spine (2015) showing suspected transitional lumbosacral vertebra, 3-4mm bilateral foraminal disc protrusion with moderately severe left greater than right neural foraminal stenosis and moderate central canal stenosis at L4-5, mild to moderate posterior element hypertrophy with a 1-2mm disc bulge with mild to moderate left greater than right neural foraminal stenosis and mild central canal stenosis at L5-S1, and a 2mm disc bulge with mild right greater than left neural foraminal encroachment with mild central canal stenosis at L3-4. There were no noted comorbidities or other dates of injury noted. On 05/20/2015, physician progress report noted complaints of constant neck pain rated 6 out of 10 in severity and radiating to both upper extremities with numbness and tingling; constant low back pain rated 6 out of 10 with radiation to both lower extremities with numbness and tingling; and constant left knee pain rated 7 out of 10. Current medications include Norco, ibuprofen, cyclobenzaprine, Terocin lotion, Terocin patches, Flurbi (NAP) cream-LA, gabacyclotram cream, Genicin, and Somnicin. The physical exam revealed restricted range of motion (ROM) in the cervical spine, restricted ROM in the lumbar spine, tenderness to palpation along the lumbar spine and paravertebral musculature bilaterally, palpable spasms along the paraspinal musculature of the lumbar spine bilaterally, negative straight leg raises bilaterally, and slightly decreased flexion of the knee. The provider noted diagnoses of cervicgia, lumbar radiculopathy, and status post left knee arthroscopy. Plan of care includes prescriptions for Norco, Genicin, Somnicin, Terocin lotion, Terocin

patches, gabaclotram, cyclobenzaprine, ibuprofen and Flurbi (NAP) cream-LA, and a follow-up in 4-6 weeks. The injured worker's work status was permanent and stationary. The request for authorization and IMR (independent medical review) includes: Norco 10-325mg #90, Genicin capsules (glucosamine sodium) 500mg #90, Somnicin capsules (Melatonin 2 mg, 5-HTP (5-hydroxytryptopan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg) #30, Terocin 240ml (0.025% capsaicin, 25% methyl salicylate, 10% menthol, 25% Lidocaine) 180gms #1, gabaclotram (10% gabapentin, 8% cyclobenzaprine, 10% tramadol) 180gms #1, Terocin patch #30, cyclobenzaprine HLC (hydrochloride) 7.5mg #60, and Flurbi (NAP) cream-LA (20% flurbiprofen, 5% Lidocaine, 4% amitriptyline) 180gm #1.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Norco 10/325mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** Hydrocodone/ Acetaminophen (Norco) is an opioid drug that is used to treat moderate to moderately severe pain. The MTUS discourages long term usage unless there is evidence of "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The MTUS also recommends the discontinuation of opioids when there is no overall improvement in function, unless there are extenuating circumstances. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. Upon review of the submitted documentation, the progress reports show that the injured worker had been prescribed Norco for more than 5 months with no decrease in pain or improvement in function. The progress reports demonstrate that the treating physician does not document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in function. Additionally, there were 3 urine drug screenings (07/2014, 09/2014 & 11/2014) with inconsistent results. As such, hydrocodone/acetaminophen (Norco) 10-325mg #90 is not medically necessary.

**Genicin capsules (Glucosamine sodium 500mg) #90:** 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), Pain, Medical Food.

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

**Decision rationale:** According to the MTUS, glucosamine sulfate is "recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulfate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH)". Additionally, The MTUS states "Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues". In this case, the injured worker has complaints of knee pain; however, there is no evidence of arthritis and no diagnosis of arthritis. Additionally, the injured worker has been prescribed and supplied this medication for several months with no evidence of reduced pain or improvement in function. As such, the requested Genicin capsules (glucosamine sodium) 500mg #90 is not medically necessary.

**Somnicin capsules (Melatonin 2mg/5HTP 50mg/L tryptophan 100mg/Pyridoxine 10mg/Mag 50mg) #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), Pain, Medical Food.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Melatonin and Other Medical Treatment Guidelines <http://sales.advancedrxmgt.com/sales-content/uploads/2012/04/Somnicin-Patient-Info-Sheet.pdf>.

**Decision rationale:** The MTUS / ACOEM and ODG do not address the use of Somnicin therefore other guidelines were consulted. A web search revealed that Somnicin (Melatonin 2 mg, 5-HTP (5-hydroxytryptopan) 50 mg, L-tryptophan 100 mg, Vitamin B6 (pyridoxine) 10 mg, Magnesium 50 mg) is an oral medication of natural ingredients which helps to promote sleep, relaxation and adequate blood flow, and may help with depression, anxiety and some pains. The ODG states that Melatonin is recommended for delayed sleep phase syndrome and rapid eye movement sleep behavior disorders. There is also some suggestion that it can have an analgesic effect, but current research is largely in the experimental phases. A review of the injured workers medical records that are available to me does not reveal that the injured worker has tried and failed other first line recommended treatments for sleep, neither is there any quantifiable improvement in sleep latency, duration or quality with the use of Somnicin, without this information it is not possible to establish medical necessity for continued use, therefore the request for Somnicin capsules (Melatonin 2mg/5HTP 50mg/L tryptophan 100mg/Pyridoxine 10mg/Mag 50mg) #30 is not medically necessary.

**Terocin 240ml (Capsaicin 0.025%, Methyl Salicylate 25%, Menthol 10%, Lidocaine 25%) 180gms QTY 1:** 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): 111-113.

**Decision rationale:** Terocin consist of Lidocaine, capsaicin, methyl salicylate and menthol. Since the MTUS is silent in regards to Terocin, the individual components of Terocin were analyzed. According to the MTUS guidelines: Topical Analgesic 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 anti-convulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants, or an AED, such as gabapentin or Lyrica). Additionally, Lidocaine is not recommended for non-neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Terocin also contains menthol and methyl salicylate. Menthol is not addressed in the MTUS or ODG; however, methyl salicylate is recommended for chronic pain. In this case, there is no documented evidence of failed trials of antidepressants and anti-convulsants. Additionally, the injured worker's diagnoses do not reflect neuropathic pain, or that neuropathic problems are the primary cause of the injured worker's pain. Furthermore, there is no documentation of inability to use an oral agents or intolerance to other treatments. As such, the request for Terocin 240ml lotion (0.025% capsaicin, 25% methyl salicylate, 10% menthol, 25% Lidocaine) 180gms #1 is not medically necessary.

**Gabaclosetam (Gabapentin 10%, Cyclobenzaprine 8%, Tramadol 10%) 180gms QTY 1:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants and Topical Analgesics Page(s): 63-66, 111-113.

**Decision rationale:** Gabaclosetam is a topical cream consisting of gabapentin, cyclobenzaprine, tramadol). According to the MTUS guidelines: Topical Analgesic 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 anti-convulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS goes on to specify that gabapentin is "not" recommended, as there

is no peer-reviewed literature to support its use. Cyclobenzaprine (brand names: Amrix, Flexeril and Fexmid; generic form: tabradol) is a centrally acting skeletal muscle relaxant. Topical cyclobenzaprine is not recommended for use as a topical agent. Tramadol is an opioid medication used to treat moderate to severe pain. Tramadol is not recommended for topical use. Although there is no recommendation regarding Gabacyclotram, one or more of the medications in Gabacyclotram are not recommended. As such, the requested gabacyclotram (10% gabapentin, 8% cyclobenzaprine, 10% tramadol) 180gms #1 is not medically necessary.

**Terocin Patch #30:** Upheld

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

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

**Decision rationale:** Terocin consist of Lidocaine, capsaicin, methyl salicylate and menthol. Since the MTUS is silent in regards to Terocin, the individual components of Terocin were analyzed. According to the MTUS guidelines: Topical Analgesic 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 anti-convulsants have failed. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants, or an AED, such as gabapentin or Lyrica). Additionally, Lidocaine is not recommended for non-neuropathic pain. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Terocin also contains menthol and methyl salicylate. Menthol is not addressed in the MTUS or ODG; however, methyl salicylate is recommended for chronic pain. In this case, there is no documented evidence of failed trials of antidepressants and anti-convulsants. Additionally, the injured worker's diagnoses do not reflect neuropathic pain, or that neuropathic problems are the primary cause of the injured worker's pain. Furthermore, there is no documentation of inability to use an oral agents or intolerance to other treatments. Moreover, there is an additional request for Terocin lotion. As such, the request for Terocin patches #30 is not medically necessary.

**Cyclobenzaprine Hydrochloride 7.5mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxant (for pain) Page(s): 41 and 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

**Decision rationale:** Per the MTUS, Cyclobenzaprine is recommended as an option in the treatment of chronic pain using a short course of therapy. It is more effective than placebo in the

management of back pain, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment suggesting that shorter courses may be better. Treatment should be brief. A review of the injured workers medical records reveal that he has been on cyclobenzaprine long term which is not consistent with the guideline recommendations, therefore the request for Cyclobenzaprine Hydrochloride 7.5mg #60 is not medically necessary.

**Flurbi (NAP) cream- LA (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 4%) 180gm**  
**QTY 1: 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 Amitriptyline, Specific Antidepressants, and Topical Analgesics Page(s): 13, 15, 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), Topical Analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants 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 (for example including, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics and/or antidepressants). Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. Flurbiprofen, used as a topical NSAID, has been shown 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. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tricyclic or SNRI anti-depressants, or an AED, such as gabapentin or Lyrica). Amitriptyline is a tricyclic antidepressant which are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. However, there is not recommendation for topical use. The topical analgesic compound (Flurbi (NAP) cream-LA) contains: 20% flurbiprofen, 5% Lidocaine and 4% amitriptyline. In this case, there is no documentation provided necessitating this compounded topical analgesic. There is no documentation of intolerance to other previous oral medications. Additionally, the injured worker has been prescribed and supplied this medication for several months with no documented evidence of functional improvement or reduction in pain with use of this medication. Therefore, the requested Flurbi (NAP) cream-LA (20% flurbiprofen, 5% Lidocaine, 4% amitriptyline) 180gm #1 is not medically necessary.