

<b>Case Number:</b>	CM15-0022630		
<b>Date Assigned:</b>	02/12/2015	<b>Date of Injury:</b>	01/10/2001
<b>Decision Date:</b>	06/04/2015	<b>UR Denial Date:</b>	01/27/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/06/2015

### 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: Anesthesiology

### 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 47 year old, male patient, who sustained an industrial injury on 01/10/2011. A primary treating office visit dated 12/11/2014 reported the patient with subjective complaint of constant neck pain that radiates to bilateral upper extremities and is rated an 8/10 in intensity. He reported the pain dropping to a 6-7 with the use of medications. Objective findings showed cervical range of motion; flexion and extension at 40 degrees, right/left rotation at 60 degrees and right/left lateral extension at 30 degrees. There is tenderness to palpation along the paravertebral muscles of the cervical spine. There is tenderness to palpation along the trapezius muscles bilaterally. Spurling's test is positive on the right. He is diagnosed with status post cervical spine surgery. The plan of care involved pending toxicology, prescribed Norco 10/325-#180, Lidoderm patches 5%, Trazadone, Flexeril, and Ibuprofen 800. Recommending continuing with home exercise program and follow up in 4-6 weeks. A request was made for Genicin, Somnicin, Norco 10/325, Flexeril, Topical Compound, Terocin patches, Terocin lotion, Capsaicin cream and Menthoderm gel. On 01/27/015, Utilization Review, non-certified the request, noting ODG Medical Food Products, CA MTUS Chronic Pain, Topical Analgesia, Compound Products, Norco, Opioids, were cited. The injured worker submitted an application for independent medical review of requested services.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Genicin #90:** Upheld

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

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

**Decision rationale:** According to the ODG, Genicin (glucosamine) is not recommended for the treatment of low back pain. Glucosamine is not significantly different from placebo for reducing pain-related disability or improving health-related quality of life in patients with chronic low back pain (LBP) and degenerative lumbar osteoarthritis, and it should not be recommended for patients with lower back pain. Glucosamine is a precursor molecule involved in building tendons, ligaments, and cartilage. It is hypothesized to restore cartilage and to have anti-inflammatory properties, and, despite conflicting data on its efficacy, has become widely used as a treatment for osteoarthritis. It has also become more widely used for LBP, including degenerative lumbar osteoarthritis. In this case, the patient has chronic neck pain and there is no indication for the use of Genicin in the treatment of chronic neck pain. Medical necessity for the requested medication has not been established. This 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) Chronic Pain, insomnia treatment.

**Decision rationale:** According to the ODG, melatonin is recommended for insomnia treatment. Melatonin also has an analgesic effect in patients with chronic pain. Somnicin contains melatonin, 5-HTP, L-tryptophan, Vitamin B6 and magnesium. There is no documentation indicating that this patient has a sleep disturbance. Medical necessity for the requested item has not been established. The requested medication is not medically necessary.

**Norco 10/325mg #180:** 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): 91-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) 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 functional benefit. 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.

**Cyclobenzaprine 10mg #30: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

**Decision rationale:** According to the reviewed literature, Cyclobenzaprine (Flexeril) is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. In addition, this medication is not recommended to be used for longer than 2-3 weeks. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than nonsteroidal anti-inflammatory medications alone. In this case, the available records show that the patient has not shown a documented benefit or any functional improvement from prior Cyclobenzaprine use. In addition, there is no clinical indication presented for the chronic or indefinite use of this medication. Based on the currently available information, the medical necessity for Cyclobenzaprine has not been established. The requested medication is not medically necessary.

**Topical Compound: Flurbi (NAP) Cream 180gms: Upheld**

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

**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, 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 Flurbi (nap) cream.

There is no documentation of intolerance to other previous medications. Flurbiprofen, used as a topical NSAID, 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. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

**Topical Compound: GabaCycloTram Cream 180gms: Upheld**

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

**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 1 non-recommended drug (or drug class) is not recommended for use. In this case, the requested compounded topical agent is Gabapentin/ Cyclobenzaprine/Tramadol cream. Cyclobenzaprine is not FDA approved for use as a topical application. There is no evidence for the use of any muscle relaxant as a topical agent. In addition, Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. . Medical necessity for the requested topical analgesic cream has not been established. The request for the compounded topical analgesic cream is not medically necessary.

**Terocin Patches #20: Upheld**

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

**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 oral medications. Medical necessity for the requested topical medication has not been established. The requested patches are not medically necessary.

**Terocin 240ml:** Upheld

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

**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 oral medications. Medical necessity for the requested topical medication has not been established. The requested topical compounded medication is not medically necessary.

**Topical Compound: Capsaicin Cream 0.025%:** Upheld

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

**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. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. Medical necessity for the requested topical analgesic cream has not been established. The request for the topical analgesic is not medically necessary.

**Menthoderm Gel 250gm:** Upheld

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

**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 drug (or drug class) that is not recommended is not recommended. In this case, Methoderm gel contains methyl salicylate and menthol. There is no peer-reviewed literature to support its use. It is also clear that the patient is able to use oral medications and there is no rationale provided for the use of topical cream. Medical necessity for the requested topical analgesic has not been established. The requested topical analgesic is not medically necessary.

**Topical Compound: Xolindo 2% 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 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 1 non-recommended drug (or drug class) is not recommended for use. In this case, there is no documentation of intolerance to other previous oral medications. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) is FDA approved for neuropathic pain, and used off-label for diabetic neuropathy. No other Lidocaine topical creams or lotions are indicated for neuropathic or non-neuropathic pain. Medical necessity for the topical analgesic cream has not been established. The requested medication is not medically necessary.