

<b>Case Number:</b>	CM15-0092689		
<b>Date Assigned:</b>	06/01/2015	<b>Date of Injury:</b>	11/10/2010
<b>Decision Date:</b>	07/03/2015	<b>UR Denial Date:</b>	05/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/13/2015

### 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: Pennsylvania

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 54 year old male who sustained a work related injury November 10, 2010. Diagnoses are herniated lumbar disc L5/S1 6mm, L4/5 4mm with radiculopathy, left shoulder sprain/strain tendinitis, impingement, rule out internal derangement, sprain/strain left ankle, rule out internal derangement, left hand sprain/strain rule out tendinitis, left hand carpal tunnel syndrome, left ankle tendinitis, degenerative joint disease with internal derangement and anterior cruciate ligament instability left knee, insomnia, and elevated blood pressure. Additional diagnoses include fractured proximal tibia, left, with open reduction and internal fixation November 2010 and hardware removed June 2012, status post (s/p) left knee MUA (manipulation under anesthesia), arthroscopy, and meniscectomy June 2012. Treatment has included surgery, epidural steroid injections, and medication. According to a primary treating physician's progress report, dated March 31, 2015, the injured worker presented with decrease in pain after steroid injection, left shoulder, March 30, 2015. The constant severe low back pain remains the same, s/p lumbar epidural injection February 21, 2015. He also reports pain in the left knee and foot. Medications include norco and lorazepam. The pain is rated 6/10 with medication and 9/10 without medication. Medications were noted to allow for activities of daily living and function, without further discussion. Examination showed decreased range of motion of the lumbar spine with tightness and spasm of the lumbar paraspinal musculature. Work status was noted as permanent and stationary/temporarily totally disabled. At issue is the request for authorization for multiple medications. On 5/7/15, Utilization Review (UR) non-certified requests for the items currently under Independent Medical Review, citing the MTUS.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% cream, 165 grams #1:** 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:** This injured worker has chronic multifocal pain. Ketoprofen, a nonsteroidal anti-inflammatory agent (NSAID), is not currently FDA approved for topical application. It has a high incidence of photo contact dermatitis. Topical NSAIDS are indicated for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment. There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. The site of application and directions for use were not specified. As topical ketoprofen is not FDA approved, it is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. As such, the request for Ketoprofen 20% cream, 165 grams #1 is not medically necessary.

**Cyclobenzaprine 5% cream, 100 grams:** 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:** Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. The treating physician has prescribed both oral and topical forms of cyclobenzaprine, which is duplicative and potentially toxic. There was no documentation of trial and failure of antidepressant and anticonvulsant medication. Due to lack of documentation of failure of a first line agent, guideline recommendation against use of topical muscle relaxants, and potential for toxicity, the request for Cyclobenzaprine 5% cream, 100 grams is not medically necessary.

**Synapryn 10 mg/1ml oral suspension 500 ml:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids p. 77-80, 93-94, glucosamine (and chondroitin sulfate) p. 50 Page(s): 77-80, 93-94, 50.

**Decision rationale:** This injured worker has chronic multifocal pain and degenerative joint disease of the knee. Synapryn contains tramadol with glucosamine in oral suspension. The reason for combining these medications is not discussed in any physician report. Given that tramadol is generally an as-needed medication to be used as little as possible, and that glucosamine (assuming a valid indication) is to be taken regularly regardless of acute symptoms, the combination product is illogical and not indicated. Tramadol is prescribed without clear evidence of the considerations and expectations found in the MTUS and similar guidelines. Opioids are minimally indicated, if at all, for chronic back pain. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient has failed a trial of non-opioid analgesics. The MTUS provides support for treating moderate arthritis pain, particularly knee OA, with glucosamine sulphate. Other forms of glucosamine are not supported by good medical evidence. The treating physician in this case has not provided evidence of the form of glucose-amine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. Should there be any indication for glucosamine in this case, it must be given as a single agent apart from other analgesics, particularly analgesics like tramadol which are habituating. Synapryn is not medically necessary based on the MTUS, lack of good medical evidence, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS.

**Tabradol 1 mg/ml oral suspension 250 ml:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine muscle relaxants Page(s): 41-42, 63-66.

**Decision rationale:** This injured worker has chronic multifocal pain, with documentation of muscle spasm on examination. Tabradol is cyclobenzaprine in an oral suspension. The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, Fexmid, Amrix, Trabadol) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. In this case, multiple additional agents have been prescribed. Limited, mixed evidence does not allow for a recommendation for chronic use. The treating physician has prescribed both oral and topical forms of cyclobenzaprine, which is duplicative and potentially toxic. Due to quantity prescribed in excess of the guideline recommendation for a short course of therapy, and potential for toxicity, the request for Tabradol 1 mg/ml oral suspension 250 ml is not medically necessary.

**Deprizine 15 mg/ml oral suspension 250 ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines GI symptoms and cardiovascular risk Page(s): 68-69.

**Decision rationale:** This injured worker has been prescribed a topical nonsteroidal, and an oral histamine-2 (H2) receptor antagonist. The MTUS recommends co-therapy of NSAIDs with a proton pump inhibitor (PPI) in patients who are determined to be at intermediate or high risk of a gastrointestinal (GI) event. There is no recommendation for H2 receptor antagonists for gastric protection from NSAID use. A H2-receptor antagonist may be considered for treatment of dyspepsia secondary to NSAID therapy. Deprizine is ranitidine in an oral suspension. Ranitidine is prescribed without any rationale provided. If ranitidine is prescribed as co therapy with an NSAID, ranitidine is not the best drug. Note the MTUS recommendations cited. There are no medical reports which adequately describe any relevant signs and symptoms of possible GI disease. Co-therapy with an NSAID is not indicated in patients other than those at high risk. No reports describe the specific risk factors present in this case. Due to lack of specific indication, the request for Deprizine 15 mg/ml oral suspension 250 ml is not medically necessary.

**Dicopanol (Diphenhydramine) 5 mg/ml 150 ml: 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).

**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.

**Decision rationale:** This injured worker was noted to have a diagnosis of insomnia. Dicopanol contains diphenhydramine and other unnamed ingredients. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Dicopanol is not medically necessary on this basis alone. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Note the Official Disability Guidelines citation above. That citation also states that antihistamines are not indicated for long term use as tolerance develops quickly, and that there are many, significant side effects. Dicopanol (Diphenhydramine) 5 mg/ml 150 ml is not medically necessary based on lack of a sufficient analysis of the patient's condition, the ODG citation, and lack of information provided about the additional unnamed ingredients.

**Fanatrex (Gabapentin) 25 mg/ml 420 ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anticonvulsants (antiepilepsy drugs (AEDs)) Page(s): 16-22.

**Decision rationale:** This injured worker has chronic back pain, with diagnosis of lumbar radiculopathy. Per the MTUS, antiepilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin (Neurontin) has been shown to be effective for treatment of diabetic neuropathy and postherpetic neuralgia and has been considered a first line treatment for neuropathic pain. The MTUS notes the lack of evidence for treatment of radiculopathy. There was no documentation of neuropathic pain for this injured worker. As such, the request for Fanatrex (Gabapentin) 25 mg/ml 420 ml is not medically necessary.