

<b>Case Number:</b>	CM15-0181498		
<b>Date Assigned:</b>	09/23/2015	<b>Date of Injury:</b>	04/22/2013
<b>Decision Date:</b>	12/29/2015	<b>UR Denial Date:</b>	08/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/15/2015

### 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: 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 52 year old female, who sustained an industrial injury on 4-22-2013. The injured worker is undergoing treatment for abdominal pain, lumbar herniated nucleus pulposus (HNP), degenerative disc disease (DDD), radiculopathy, bilateral knee meniscal tear, osteoarthritis, joint effusion, and right knee anterior cruciate ligament (ACL) tear. Medical records dated 7-10-2015 indicate the injured worker complains of abdominal pain, burning radicular back pain and spasm rated 5 out of 10 with numbness and tingling in the legs and knee pain rated 5 out of 10. Physical exam dated 7-10-2015 notes ambulation with a cane, lumbar tenderness to palpation and spasm with decreased range of motion (ROM). There is bilateral knee effusion, tenderness to palpation and positive McMurray's test. Treatment to date has included magnetic resonance imaging (MRI), rest, injections and medication. The original utilization review dated 8-26-2015 indicates the request for Ketoprofen cream, cyclobenzaprine cream, Synapryn suspension, Tabradol suspension, Deprizine suspension, Dicopanol suspension and Fanatrex suspension is non-certified.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% cream 167 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The CA MTUS Chronic Pain Guidelines indicate that topical analgesics are "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." They are "largely experimental in use with few randomized controlled trials to determine effectiveness or safety." Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). The MTUS indicates that topical NSAIDs may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Note that topical Ketoprofen is not FDA approved for topical application. Non-FDA approved medications are not medically necessary. The only FDA-approved topical NSAIDs are diclofenac formulations. All other topical NSAIDs are not FDA approved. The guidelines indicate that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The requested treatment: Ketoprofen 20 Percent Cream is not medically necessary.

**Cyclobenzaprine 5% cream 110 grams:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain), Topical Analgesics.

**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 Cyclobenzaprine 5 Percent Cream. Cyclobenzaprine is a centrally acting skeletal muscle relaxant and is not recommended for topical application. There is no peer-reviewed literature to support its use. There is no clear documentation in the submitted Medical Records that the injured worker has failed a trial of antidepressants and anticonvulsants. Medical necessity for the requested topical medication has not been established. The requested treatment Cyclobenzaprine 5 Percent Cream is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OMFS 1997 page 7.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate), Opioids, criteria for use, Opioids for chronic pain.

**Decision rationale:** Synapryn is combination of tramadol and glucosamine. The reason for combining these medications is not discussed in any physician report. Given that tramadol is generally a prn 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 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. 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 glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. And 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. The requested treatment: Synapryn 10mg/ml oral suspension 500ml is not medically necessary and appropriate.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OMFS 1997 page 7.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter --Muscle relaxants.

**Decision rationale:** 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. This patient has chronic pain with no evidence of prescribing for flare-ups, and the pain is located in multiple areas. The MTUS states that treatment with cyclobenzaprine should be brief, and that the addition of cyclobenzaprine to other agents is not recommended. In this case, the oral suspension form plus topical is experimental and unproven. Prescribing was not for a short term exacerbation. Per the MTUS, cyclobenzaprine is not indicated. The requested treatment: Tabradol is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OMFS 1997 page 7.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Deprizine is ranitidine in an oral suspension. 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. If ranitidine is prescribed as co-therapy with an NSAID, ranitidine is not the best drug. 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. Medical necessity of the requested item has not been established, therefore is not medically necessary.

**Dicopanol (diphenhydramine) 5mg/ml oral suspension 150ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OMFS 1997 page 7.

**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:** Official Disability Guidelines (ODG) state Over-the-counter medications: Sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. Dicopanol is diphenhydramine and other proprietary 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. Official Disability Guidelines state that antihistamines are not indicated for long term use as tolerance develops quickly, and that there are many, significant side effects. MTUS states Medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. Dicopanol is not medically necessary based on lack of a sufficient analysis of the patient's condition, and lack of information provided about the ingredients. The requested medication: Dicopanol 5 MG/ML 150 ML is not medically necessary.

**Fanatrex (gabapentin) 25mg/ml oral suspension 420ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-Anti-epilepsy drugs (AEDs) for pain.

**Decision rationale:** Per the MTUS, Fanatrex (gabapentin) is a compounded form of an anti-epilepsy drug (AEDs - also referred to as anti-convulsants). These drugs have been shown to be effective for treatment of diabetic painful neuropathy/polyneuropathy and postherpetic neuralgia and have been considered as a first-line treatment for neuropathic pain. FDA-approved drugs should be given adequate trial, if these are inadequate, ineffective or contraindicated in the individual patient, and then compounded drugs with FDA-approved ingredients can be considered. The clinical documentation submitted for review does not indicate diagnoses of diabetic neuropathy or postherpetic neuralgia. Within the submitted records, there is no indication for the compounded oral suspension form of this drug in such a low dose (non-therapeutic dose) in comparison to the recommended dose of oral gabapentin in tablet form. In addition, there is no documented failed trial of the FDA-approved form of this drug, and no indication as to the reason that the FDA-approved form is contraindicated in the injured worker. As such, the request for Fanatrex (gabapentin) 25mg/ml 420ml is not medically necessary and appropriate.