

<b>Case Number:</b>	CM14-0012458		
<b>Date Assigned:</b>	02/21/2014	<b>Date of Injury:</b>	05/10/2013
<b>Decision Date:</b>	08/07/2014	<b>UR Denial Date:</b>	01/07/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/30/2014

### 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. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient is a 35-year-old female who has filed a claim for lumbar disc displacement associated with an industrial injury date of May 10, 2013. Review of progress notes indicates low back pain, and resolved right wrist pain. Findings of the lumbar spine include decreased range of motion, muscle spasm, positive Lasgue's on the right, and positive sacroiliac distraction and compression test. An MRI of the right wrist dated October 18, 2013 showed small radiocarpal and ulnocarpal joint effusion. An MRI of the lumbar spine dated June 13, 2013 showed mild degenerative changes of the L4-5 and L5-S1 discs, and posterior osteophyte disc complexes at L4-5 and L5-S1. Treatment to date has included physical therapy, NSAIDs, topical analgesics, Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, acupuncture, and hot and cold packs.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compounded Ketoprofen (20% 120-grams): 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:** According to the Chronic Pain Medical Treatment Guidelines, many agents are compounded as monotherapy or in combination for pain control. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen is not currently FDA-approved for topical application. It has an extremely high incidence of photocontact dermatitis. There is no documentation of failure of or intolerance to oral pain medications. In addition, ketoprofen is not recommended for topical use. There is no discussion concerning the need for variance from the guidelines. Therefore, the request is not medically necessary.

**Compounded Cyclophene (5% - 120-grams): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41,64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112-113.

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Dicopanol is diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. There is no documentation regarding sleep issues in this patient. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request is not medically necessary.

**Synapryn (10mg/1ml - 500mg): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Classification Tramadol (Ultram) Page(s): 93.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate), Opioids, specific drug list, Tramadol Page(s): 50; 93. Decision based on Non-MTUS Citation National Library of Medicine's DailyMed Database (dailymed.nlm.nih.gov).

**Decision rationale:** A search of online resources revealed that Synapryn contains tramadol hydrochloride 10mg/mL, in oral suspension with glucosamine - compounding kit. Tramadol is indicated for moderate to severe pain. The Chronic Pain Medical Treatment Guidelines states that Glucosamine and Chondroitin Sulfate are recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Additionally, this drug has not been found by FDA to be safe and effective, and is not approved by the FDA. Furthermore, there is no clear rationale identifying why a compound/oral suspension (as opposed to the evidence based guidelines supported and FDA approved non-compounded medication) is needed for this patient. Therefore, the request is not medically necessary.

**Tabradol (1mg - 250ml): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain), Cyclobenzaprine Page(s): 41,64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42. Decision based on Non-MTUS Citation National Library of Medicine's DailyMed Database (dailymed.nlm.nih.gov).

**Decision rationale:** Tabradol is cyclobenzaprine hydrochloride with methylsulfonylmethane (MSM) in oral suspension. The Chronic Pain Medical Treatment Guidelines state that cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant that is recommended as a short-course therapy. The effect is greatest in the first 4 days of treatment. There is no documentation regarding intolerance to cyclobenzaprine in tablet form. In addition, MSM is not FDA approved. Therefore, the request is not medically necessary.

**Deprizine (15mg/ml - 250ml):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment Index, 9th Edition (web), 2011, Chronic Pain - Medical food, and on the website Meds.com.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation website Drugs.com.

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. There is no documentation regarding upper GI symptoms or risk factors. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request is not medically necessary.

**Dicopanor (Diphenhydramine) (5 mg/1ml -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, Treatment Index, 9th Edition (web), 2011, Chronic Pain - Medical food, and on the website Meds.com.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation website Drugs.com.

**Decision rationale:** The California MTUS Guidelines do not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Dicopanor is diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. There is no documentation regarding sleep issues in this patient. In addition, there is no rationale

provided for the medical necessity of an oral suspension. Therefore, the request is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18-20.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-18.

**Decision rationale:** Fanatrex is gabapentin with other proprietary ingredients in oral suspension. According to the Chronic Pain Medical Treatment Guidelines, gabapentin is useful for treating diabetic painful neuropathy and postherpetic neuralgia, and is considered first-line for neuropathic pain. The patient does not present with neuropathic pain. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Fanatrex (gabapentin) 25mg/ml 420ml was not medically necessary.

**Urine Analysis Toxicological Evaluation: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Steps to Avoid Misuse/Addiction Page(s): 94-95.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-Going Management Page(s): 78.

**Decision rationale:** According to the Chronic Pain Medical Treatment Guidelines, urine drug screens are recommended as an option to assess order use or presence of illegal drugs and as ongoing management for continued opioid use. In this case, there is documentation of monthly urine drug screens from September to November 2013, which tested negative for all substances. There is no indication for frequent monitoring in this patient, as there is no evidence to suspect aberrant drug use behaviors. In addition, the requested medications are not authorized, and the patient is not currently on opioid therapy. Therefore, the request is not medically necessary.