

<b>Case Number:</b>	CM13-0056939		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	09/15/2010
<b>Decision Date:</b>	03/21/2014	<b>UR Denial Date:</b>	10/11/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/25/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine, and is licensed to practice in California. 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 physician 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:

This is a 29 year-old female who was injured on 9/15/2010 when she was taking out a 40-pound trash bag and had a pop in her right wrist and had pain in the right shoulder. According to the 10/2/13 report from [REDACTED], she still has 7-9/10 pain in the right shoulder and wrist, and is awaiting authorization for a right wrist surgery. Her diagnosis is right wrist CTS, and right shoulder internal derangement. On 10/11/13 UR recommended non-certification for the compounded topical and oral suspension medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**One prescription of compounded Ketoprofen 20% in PLO gel 120 grams between 9/27/13 and 11/24/2013: Upheld**

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

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

**Decision rationale:** The employee presents with right shoulder pain and right CTS. I am asked to review a compound topical that contains Ketoprofen. The MTUS Guidelines state "Any

compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The MTUS Guidelines specifically state ketoprofen is not FDA approved for topical applications. Any compounded topical product containing ketoprofen would not be recommended.

**One prescription of compounded Cyclophene 5% PLO gel 120 grams between 9/27/13 and 11/24/2013: Upheld**

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

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

**Decision rationale:** The employee presents with right shoulder pain and right CTS. The MTUS Guidelines state "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The topical compound Cyclophene is reported to contain cyclobenzaprine, a muscle relaxant. The MTUS Guidelines discuss topical muscle relaxants noting a study on baclofen, but states: "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." The use of Cyclophene is not in accordance with MTUS guidelines

**One prescription of Synapryn 10mg/1ml oral suspension 500ml between 9/27/13 and 11/24/2013: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 82, 93-94,111-113.

**Decision rationale:** The employee presents with right shoulder pain and right CTS. The compounded medication is reported to contain tramadol and glucosamine and other ingredients. The MTUS Guidelines in general for compounded medications states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The strict application of MTUS guidelines would not allow this compound as the product contains "other proprietary ingredients". The "other ingredients" are not specified and would be necessary in order to compare to MTUS criteria. With the unknown "proprietary ingredients", I cannot verify that the request is in accordance with MTUS guidelines.

**One prescription of Deprizine 15mg/ml oral suspension 250ml between 9/27/13 and 11/24/2013: Upheld**

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

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

**Decision rationale:** The employee presents with right shoulder pain and right CTS. There is no discussion as to why the employee is not able to take the traditional oral form of the H2-receptor antagonist. There is no reported history of GI bleed, peptic ulcer, or high dose or multiple NSAID, or anticoagulants. The employee does not appear to have any of the MTUS risk factors for GI events that would support the use of ranitidine for prophylactic use. The use of oral form or tablet form of ranitidine is not in accordance with MTUS guidelines.

**One prescription of Tabradol 1mg/ml oral suspension 250ml between 9/27/13 and 11/24/2013:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 37-38, 41-42, 63.

**Decision rationale:** The employee presents with right shoulder pain and right CTS. The request before me is for tabradol which is a compounded oral suspension of cyclobenzaprine and MSM. The MTUS Guidelines in general state "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Tabradol is reported to contain MSM; MSM is not FDA approved for medical treatment of any condition. . The MTUS guidelines under MSM redirects the reader to DMSO for treatment of a regional inflammatory reaction with CRPS. The employee does not have CRPS. Tabradol would not be recommended under MTUS criteria. MTUS also states, under cyclobenzaprine, that it is not recommended to add cyclobenzaprine to other agents. The request is not in accordance the MTUS guidelines.

**One prescription of Dicopanl 5mg/ml oral suspension 150ml between 9/27/13 and 11/24/2013:** 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).

**Decision rationale:** The employee presents with right shoulder pain and right CTS. The employee has been provided Dicopanl, a compounded oral suspension with diphenhydramine and "other proprietary ingredients", since 2/22/13. There has been no reporting of efficacy or description of what the proprietary ingredients are. The ODG guidelines indicate sleep disturbance that does not resolve in 7-10 days may indicate a psych injury or medical illness, and that "Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance". The records do not show a careful evaluation, and show that the medication

continues to be recommended even without subjective complaints of insomnia. The ODG does not recommend long-term use of sleep medications, and Dicoprofanol does not appear to be recommended by MTUS guidelines. On page 111, under topical analgesics, MTUS gives a general statement about compounded products: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended". The strict application of MTUS guidelines would not allow this compound as the product contains "other proprietary ingredients". The "other ingredients" are not specified and would be necessary in order to compare to MTUS criteria. With the unknown "proprietary ingredients", they cannot be verified to be in accordance with MTUS guidelines.

**One prescription of Fanatrex 25mg/ml oral suspension 420ml between 9/27/13 and 11/24/2013: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113,16-18;.

**Decision rationale:** The employee presents with right shoulder pain and right CTS. I am asked to review for Fanatrex. Fanatrex is a compounded oral suspension. The compound includes gabapentin, and "other proprietary ingredients". There is no discussion as to why the employee cannot take the tablet form of gabapentin, and the employee on 9/27/13 complains that the elixirs cause nausea and vomiting. The MTUS Guidelines in general for compounded medications, page 111 states "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The "other proprietary ingredients" are not disclosed. Since components of "other proprietary ingredients" are unknown, they cannot be compared against MTUS criteria, and therefore cannot be confirmed to be in accordance with MTUS.

**One periodic urine analysis toxicological evaluation between 9/27/13 and 11/24/2013: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009), pg. 32.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), ODG-TWC Guidelines.

**Decision rationale:** The employee presents with right shoulder pain and right CTS. The employee is not taking any narcotic analgesics. The employee had negative UDTs on 5/31/13 and 7/29/13. There is no discussion that the employee is above low risk for aberrant drug behavior. The issue appears to be the frequency of UDT. The MTUS does not specifically

discuss the frequency that UDT should be performed. The ODG is more specific on the topic and states: "Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only." The ODG guidelines state that for patients at low risk, testing can be within 6 months of initiation of therapy, then on a yearly basis thereafter. The request for UDT is not in accordance with the frequency listed under ODG guidelines