

<b>Case Number:</b>	CM13-0066061		
<b>Date Assigned:</b>	02/11/2014	<b>Date of Injury:</b>	09/05/2012
<b>Decision Date:</b>	05/20/2014	<b>UR Denial Date:</b>	11/13/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/09/2013

### 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 Physical Medicine & Rehabilitation and is licensed to practice in Texas. 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 injured worker reported injury on 09/05/2012. The specific mechanism of injury was not provided. The documentation of 09/30/2013 revealed the injured worker's mechanism of injury was cumulative trauma. The injured worker's pain was a 3/10 that was constant and moderate to severe. The injured worker had complaints of numbness, weakness, tingling, and pain radiating to the hands and the 3 middle fingers. The physical examination revealed there was tenderness to palpation over the carpal bones and along the distribution of the median nerve. The injured worker had decreased range of motion of the bilateral wrists and had positive Finkelstein's tests. The injured worker had decreased sensation bilaterally along the course of the median nerve. The motor strength in the bilateral upper extremities was decreased secondary to pain. The diagnoses include bilateral wrist sprain/strain, rule out carpal tunnel syndrome, and rule out de Quervain's tenosynovitis. The recommendation was for Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclophene, and Ketoprofen cream. Additionally, it was recommended the injured worker received carpal tunnel brace and hot paraffin therapy for bilateral hands, as well as shockwave therapy for the bilateral wrists. The documentation of 11/01/2013 refilled the medication compounded Ketoprofen and Cyclophene. It additionally refilled Dicopanol, Deprizine, Fanatrex, Synapryn, and Tabradol.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUNDED CYCLOPHENE 5 % IN PLO GEL 120 GMS #1: 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, Muscle Relaxants and Cyclobenzaprine Page(s): 111,113,41.

**Decision rationale:** California MTUS indicates topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain and the injured worker had trialed and failed antidepressants and anticonvulsants. The clinical documentation indicated the injured worker had been utilizing the medication since 09/2013. There was lack of documented objective functional improvement and objective decrease in pain. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for compounded Cyclophene 5% in PLO gel 120 grams #1 is not medically necessary.

**DICOPANOL 5MG/ML ORAL SUSPENSION 150ML 1 ML PO HS #1:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guideline, Insomnia Treatment.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Dicopanол>.

**Decision rationale:** Per Drugs.com, Dicopanол is diphenhydramine hydrochloride and it was noted this drug has not been found by the FDA to be safe and effective and the labeling was not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the Dicopanол was for insomnia. The clinical documentation indicated the injured worker had been utilizing the medication since 09/2013. There was no documentation of the efficacy of the medication. The request would not be supported. There was no documentation indicating the injured worker could not tolerate or swallow a pill. Given the above, the request for Dicopanол 5 mg/ml oral suspension 150 ml, 1 ml by mouth at bedtime, #1 is not medically necessary.

**DEPRIZINE 5MG/ML ORAL SUSPENSION 250ML 10ML OD #1:** Upheld

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

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

**Decision rationale:** California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated the medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation indicated the injured worker had been utilizing the medication since 09/2013. The clinical documentation submitted for review failed to indicate the injured worker had signs and symptoms of dyspepsia secondary to NSAID therapy. There was a lack of documentation indicating the necessity for a liquid form of the medication. Given the above, the request for Deprizine 5 mg/ml oral suspension 250 ml, 10 ml OD, #1 is not medically necessary.

**COMPOUNDED KETOPROFEN 20% IN PLO GEL 120GMS #1:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics and Ketoprofen Page(s): 111,113.

**Decision rationale:** California MTUS indicates Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Ketoprofen is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. Additionally, as Ketoprofen is not FDA-approved for topical application, the request would not be supported. The clinical documentation indicated the injured worker had been utilizing the medication since 09/2013. There is a lack of documentation of objective functional benefit received from the medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for compounded Ketoprofen 20% in PLO gel 120 grams, #1 is not medically necessary.