

<b>Case Number:</b>	CM14-0001220		
<b>Date Assigned:</b>	01/22/2014	<b>Date of Injury:</b>	09/10/2008
<b>Decision Date:</b>	03/27/2014	<b>UR Denial Date:</b>	12/11/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/03/2014

### 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 Family Practice, 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 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:

The patient is a 48-year-old female who reported an injury on 09/10/2008. The mechanism of injury was not provided. The patient's diagnoses were noted to include cervicalgia/cervical radiculopathy/status post left shoulder arthroscopy with residual pain/lumbar radiculopathy. The patient had subjective complaints of pain over multiple areas of her body ranging from 2/10 to 6/10. The 1 note submitted for the requested medications was from an Electromyography (EMG)/Nerve Conduction Velocity (NCV), along with a physical examination on 12/11/2013. The patient was noted to have 58 chiropractic care visits, along with physiotherapy. The request for the medications was not provided, however per the submitted form, the request was made for Synapryn 10 mg/mL oral suspension 500 mL, Tabradol 1 mg/mL oral suspension 250 mL, Deprizine 15 mg/mL oral suspension 260 mL, and Dicoprofanol 5 mg/mL oral suspension. The duration of use was not provided.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**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 (ODG) Official Disability Guidelines, Chronic Pain: Medical Compound Drugs

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate Ongoing Management Tramadol Page(s): 50, 78, 82, 93-94.

**Decision rationale:** California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. A thorough search of FDA.gov did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption. California MTUS guidelines recommend Glucosamine Sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only one medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. Clinical documentation submitted for review failed to provide the necessity for an oral suspension which included tramadol and glucosamine sulfate. California MTUS guidelines also indicate there should be documentation of the patient's analgesia, activities of daily living, adverse side effects and that the patient is being monitored for aberrant drug taking behavior. Clinical documentation submitted for review failed to provide exceptional factors to warrant nonadherence to guideline recommendations. There was a lack of documentation indicating the level of the patient's analgesia, increased activities of daily living, and adverse side effects, and there was a lack of documentation indicating the patient was being monitored for aberrant drug taking behavior. Given the above, the request for Synaprin 10 mg/mL oral suspension 500 mL is not medically necessary.

**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 (ODG) Official Disability Guidelines, Chronic Pain: Medical Compound Drugs

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

**Decision rationale:** The California MTUS indicate that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California MTUS guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. Given the lack of evidence based literature for the oral compounding of cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications, Tabradol 1mg/ml oral suspension 250ml is not medically necessary.

**Deprizine 15mg/ml oral suspension 260ml:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines, Chronic Pain: Medical Compound Drugs

**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 clinical documentation submitted for review failed to indicate the patient had signs and/or symptoms of dyspepsia. Additionally, there was a lack of documentation indicating exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for Deprizine 15 mg/mL oral suspension 260 mL is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines, Chronic Pain: Medical Compound Drugs

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

**Decision rationale:** Per Drugs.com, Dicopanol 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 clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to FDA regulations. The request as submitted failed to indicate a quantity of medication being requested. Given the above, the request for Dicopanol (diphenhydramine) 5mg/ml oral suspension is not medically necessary.