

<b>Case Number:</b>	CM15-0061340		
<b>Date Assigned:</b>	04/07/2015	<b>Date of Injury:</b>	06/09/2014
<b>Decision Date:</b>	05/29/2015	<b>UR Denial Date:</b>	03/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/31/2015

### 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: California  
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 34 year old female, who sustained an industrial injury on June 9, 2014. The mechanism of injury was noted to be the injured worker was placing boxes on top of a conveyor belt and her left hand was pulled in the rubber belt of the conveyor line. She has reported shoulder pain, head pain, jaw pain, neck pain, wrist pain, hand pain, finger pain, and back pain. Diagnoses have included cervical spine radiculopathy, cervical spine pain, bilateral shoulder pain, right wrist pain, left finger deformity, left hand pain, lower back pain, radiculitis of the lower extremity, lumbar spine disc displacement, cervical spine disc displacement, acute flagrant reflex sympathetic dystrophy of the left upper extremities with a non-functional left palm and hand and left jaw pain. Treatment to date has included medications, physical therapy, and imaging studies. A progress note dated February 5, 2015 indicates a chief complaint of left jaw pain, neck pain with numbness and tingling of the bilateral arms, bilateral shoulder pain, right wrist pain with weakness, numbness and tingling of the hand and fingers, left hand and finger pain, and lower back pain with numbness and tingling of the bilateral legs. The treating physician documented a plan of care that included medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn 10mg/1ml oral suspension 500ml: 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:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, 94. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Synapryn online drug insert.

**Decision rationale:** The California Medical Treatment Utilization Schedule Guidelines recommend tramadol for pain; however, do not recommend it as a first line oral analgesic and they recommend glucosamine sulfate for patients with moderate arthritis pain especially, knee osteoarthritis and that only 1 medication should be given at a time. Synapryn per the online package insert included tramadol and glucosamine sulfate. 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. As tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule Chronic Pain Guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review failed to provide documentation that the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation failed to indicate the injured worker had an objective decrease in pain and objective functional improvement with the use of the medication. There was a lack of documentation indicating the injured worker was being monitored for aberrant drug behavior. There was documentation the injured worker was being monitored for side effects. The request as submitted failed to indicate the frequency and the dosage for the requested medication. Given the above, the request for Synapryn 10 mg/1 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 Official Disability Guidelines (ODG).

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

**Decision rationale:** Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California Medical Treatment Utilization Schedule Guidelines and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database returned no discussion on Tabradol. 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. There was a 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. The clinical

documentation submitted for review failed to provide documentation the injured worker could not swallow or tolerate a pill. There was a lack of documentation of exceptional factors. The request as submitted failed to indicate the frequency and the specific dosage being requested. Given the above, the request for Tabradol 1 mg/mL oral suspension 250 mL 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 Official Disability Guidelines (ODG).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Deprizine>.

**Decision rationale:** The California Medical Treatment Utilization Schedule Guidelines recommends histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine which is a histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine: Generic Name: ranitidine hydrochloride has not been found by FDA to be safe and effective, and this labeling has not been approved by 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 failed to indicate the injured worker had dyspepsia. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency and specific dosage for the requested medication. Given the above, the request for Deprizine 15 mg/mL oral suspension 250 mL is not medically necessary.

**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 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) Pain Chapter, Insomnia Treatments.

**Decision rationale:** The Official Disability Guidelines indicate that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. 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 failed to document the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation indicating the injured worker had difficulty with sleep. The request as submitted failed to indicate the frequency and the specific dosage being requested.

Given the above, the request for diphenhydramine 5 mg/mL oral suspension is not medically necessary. Additionally, the request as submitted failed to indicate the specific quantity of medication being requested. Therefore, the requested treatment is not medically necessary.