

<b>Case Number:</b>	CM14-0202939		
<b>Date Assigned:</b>	12/15/2014	<b>Date of Injury:</b>	04/06/2012
<b>Decision Date:</b>	03/10/2015	<b>UR Denial Date:</b>	11/10/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/04/2014

### 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. 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, Washington

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

### 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 54 year old female sustained a work related injury on 04/06/2012. The mechanism was not provided. Other therapies included physical therapy, chiropractic therapy and shockwave therapy. As of a progress report dated 10/18/2014, the injured worker complained of burning, radicular neck pain and muscle spasms, burning of the bilateral shoulders radiating down the arms to the fingers associated with muscle spasms, bilateral elbow pain and muscle spasms, burning bilateral wrist pain and muscle spasms, burning radicular mid back pain and muscle spasms, burning bilateral knee pain and muscle spasms, and burning bilateral feet pain and muscle spasms. Pain in these areas was rated an 8 on a scale of 0-10. Of note, her pain level was rated less on a previous visit dated 09/10/2014. She also complained of stomach problems associated with nervousness, headaches and difficulty sleeping. Diagnoses included cervical spine multilevel HNP, cervical spine multilevel degenerative disc disease, cervical spine radiculopathy, bilateral shoulder impingement syndrome, bilateral shoulder rotator cuff tear, bilateral shoulder tenosynovitis, bilateral shoulder AC joint osteoarthropathy, left elbow sprain/strain, right elbow tear of common extensor tendon, right elbow lateral epicondylitis, bilateral wrist carpal tunnel syndrome, bilateral wrist subchondral cyst, thoracic spine multilevel HNP, thoracic spine multilevel degenerative disc disease, bilateral knee sprain/strain, right knee chondromalacia patellae, right knee osteoarthritis, bilateral knee medial meniscal tear, bilateral plantar fasciitis, anxiety disorder, mood disorder, sleep disorder, headaches and abdominal discomfort. Treatment plan included periodic urinalysis toxicological evaluation, PRP treatment for the right and left shoulder, continue with course of acupuncture, continue with the course of

shockwave therapy, MRI of the right and left shoulder, right and left elbow, right and left wrist, bilateral knees and cervical, thoracic and lumbar spine, Terocin patches. Medication listed included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Flurbiprofen, Menthol, Cyclobenzaprine and Gabapentin. On 11/10/2014, Utilization Review non-certified Tabradol 1mg/ml oral suspension 250ml three times a day, Deprizine 15mg/ml oral suspension 250ml, Docopanol 5mg/ml oral suspension 150ml and Synapryn 10mg/ml oral suspension 550 ml three times a day. The request was received on 10/24/2014. According to the Utilization Review physician in regards to Synapryn, documentation noted that the medication offered temporary relief. It also did not indicate why the injured worker was unable to take oral capsules or tablets requiring the use of a compound oral suspension. CA MTUS Guidelines state that there should be ongoing review and documentation of pain relief, functional status, appropriated medication use and side effect for patients taking narcotic analgesics. The pain assessment should include current pain, pain over the period since the last assessment, average pain, and intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain relief lasts. In regards to Tabradol, records indicated that the injured worker had been taking the medication since August 2014. There was no indication why the injured worker was unable to take oral capsules or tablets. Guidelines recommend non-sedating muscle relaxant with caution as a second line option for short term treatment of acute exacerbation in patients with chronic low back pain. Cyclobenzaprine is not recommended to be used longer than 2-3 weeks. In regard to Dicopanol, long term use is not recommended and side effect likely outweighs the benefits. There were also no records to indicate why the injured worker was unable to take oral capsules or tablets. Guidelines cited for this review included CA MTUS Chronic Pain Medical Treatment Guidelines pages 78-80, 93-94, 124 Opioids, page 50 Glucosamine, pages 63-64 Muscle Relaxants and page 69 NSAIDS and Official Disability Guidelines Insomnia Treatment. The decision was appealed for an Independent Medical Review.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Tabradol 1mg/ml oral suspension 250ml Tid: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant Page(s): 63-64.

**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. There was a lack of

documentation of exceptional factors to warrant nonadherence to guideline recommendations. The injured worker's current medications included Tabradol. However, the efficacy was not provided. There was a lack of documentation of objective functional improvement, an objective decrease in pain, and that the injured worker had a necessity for a liquid versus a tablet for a muscle relaxant. Additionally, the injured worker was utilizing an oral muscle relaxant as well. There was a lack of documentation indicating a necessity for both an oral tablet and an oral liquid for treatment. Given the above, the request for Tabradol 1 mg/mL oral suspension 250 mL TID is not medically necessary.

**Deprizine 15mg/ml oral suspension 250ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67.

**Decision rationale:** The California Medical Treatment Utilization Schedule guidelines not specifically address Deprizine, however it does address H-2 Blockers. The California Medical Treatment Utilization Schedule Guidelines recommend 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. There was a lack of documentation of exceptional factors to support the use of this medication. This was noted to be a current medication and the efficacy was not provided. Given the above, the request for Deprizine 15mg/ml oral suspension 250ml was not medically necessary.

**Dicopanor (Diphenhydramine) 5mg/ml oral suspension 150ml: 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) Insomnia

**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, does not specifically address Dicopanor, but do address diphenhydramine.

**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. Per Drugs.com, Dicopanor 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. There was a lack of documentation of exceptional factors. Given the above, the request for Dicopanor (Diphenhydramine) 5mg/ml oral suspension 150ml is not medically necessary.

**Synapryn 10mg/1ml oral suspension 500ml Tid: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-94; 124.

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

**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 one 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. There was a lack of documentation indicating the injured worker could not utilize a tablet or capsule and this medication was noted to be a current medication. As such, there was a lack of documentation of objective functional benefit, an objective decrease in pain and documentation that the injured worker was being monitored for aberrant drug behavior and side effects. Given the above, the request for Synapryn 10mg/1ml oral suspension 500ml TID is not medically necessary.