

<b>Case Number:</b>	CM13-0059348		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	12/12/2007
<b>Decision Date:</b>	04/03/2014	<b>UR Denial Date:</b>	11/01/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/02/2013

### 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 and Rehabilitation has a subspecialty in Pain Medicine 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:

The patient is a 50 year old male who was injured on 12/12/2007 when he was knocked off the forklift he used for managing a deliver and fell approximately 4 ft down, landing on his back and rolling to the left side of his body. Treatment history has included physical therapy, acupuncture treatments and pain medications. Toxicology report dated 01/05/2013 was negative for all drugs tested and consistent with prescribed medications that were listed. Urine toxicology review dated 10/30/2013 indicated negative results for all drugs tested. Toxicology report dated 12/30/2013 indicated no medications were tested nor detected. Special Comprehensive Primary Treating Physician's Report dated 11/10/2013 documented the patient to have complaints of burning, radicular neck pain and muscle spasms for which he rated the pain as 8/10. He had burning bilateral shoulder pain radiating down the arm to the fingers, associated with muscle spasms. He rated the pain as 8/10. The patient complained of burning left wrist pain for which he rated the pain as 5-6/10; burning, radicular low back pain and muscle spasms. He rated the pain as 8/10; burning left hip pain, pain rated as 8/10; burning bilateral ankle pain, pain rated as 5-6/10. He had tenderness of the cervical spine. Ranges of motion of the cervical spine slightly decreased; bilateral shoulder exam revealed tenderness; Ranges of motion of the bilateral shoulders within normal limits. Motor strength decreased secondary to pain. Deep tendon reflexes were 2+ and symmetrical in the bilateral upper extremities. The patient used a can for walking. He was able to heel-toe walk; however, he had pain with heel walking. He had tenderness to palpation with spasms noted at the lumbar paraspinal muscles. Straight leg raise was positive at 40 degrees bilaterally. There was tenderness to palpation at the greater trochanters; Ranges of motion of the left hip were within normal limits. On knee exam, he had tenderness to palpation over the medical and lateral joint line; Ranges of motion of bilateral knees were within normal limits; Ranges of motion of the bilateral ankles were within normal

limits. Motor strength decreased at the bilateral lower extremities secondary to pain. Deep tendon reflexes were 2+ and symmetrical in the bilateral lower extremities. Recommendations were medications, continue with the course of physical therapy and acupuncture therapy, undergo a course of shockwave therapy and Terocine Patches.

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

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

#### **Compound Ketoprofen 20% in PLO gel, 120 gm: Upheld**

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

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

**Decision rationale:** As per CA MTUS guidelines, topical NSAIDs are not recommended due to the efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Also, Ketoprofen is not currently FDA approved for topical application. The request is not supported by the guidelines and hence the request compound Ketoprofen 20% in PLO gel, 120 gm is non-certified.

#### **Compound Cyclophene 5% in PLO gel, 120 gm: Upheld**

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

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

**Decision rationale:** Cyclophen is cyclobenzaprine, a muscle relaxant and as per CA MTUS guidelines, there is no evidence supporting use of muscle relaxants as a topical product. Thus, the request is non-certified.

#### **Synapryn 10 mg/ml 500 ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [dailymed.nlm.nih.gov/dailymed/archives/fdaDruginfo.cfm?archived=22416](http://dailymed.nlm.nih.gov/dailymed/archives/fdaDruginfo.cfm?archived=22416)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 76-82.

**Decision rationale:** Synapryn contains tramadol hydrochloride and glucosamine. As per CA MTUS guidelines, four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning,

and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The records submitted do not demonstrate that this patient has demonstrated objective functional improvement, increased functional activities, or reduction in pain level. This patient had several urine drug screening performed and the results showed no compliance with prescribed medications. Further, the combination of the ingredients in synapryn has not been approved for use. Thus, the request for Synapryn 10 mg/ml 500 ml is not medically necessary and is non-certified.

**Tabradol 1 mg/ml 250ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.drugs.com/pro/diphenhydramine.html](http://www.drugs.com/pro/diphenhydramine.html)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Page(s): 41-42, 64.

**Decision rationale:** Tabradol contains metylsulfonylmethane (MSM), and cyclobenzaprine. As per CA MTUS guidelines, cyclobenzaprine is recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. It is recommended for short-term treatment of acute exacerbations in patients with chronic low back pain. The guidelines further note that cyclobenzaprine is not recommended to be used longer than 2-3 weeks. Records submitted indicated that this patient has chronic neuropathic pain and there is documentation of acute exacerbation of the lower back pain. Additionally, it is unclear why the employee is unable to take a pill or capsule orally, and as such, the request for Tabradol 1 mg/ml oral suspension 250 ml is not medically necessary and is non-certified.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.drugs.com/pro/diphenhydramine.html](http://www.drugs.com/pro/diphenhydramine.html)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** As per CA MTUS guidelines, Deprizine suspension contains Ranitidine, an H2 receptor antagonist which can be considered when there is concurrent use of SSRI's and NSAIDs which have excess relative risk of serious upper GI events. Records submitted revealed no documentation of subjective or objective GI events or ulcers to warrant the use of this medication. Additionally, it is unclear why the employee is unable to take a pill or capsule orally. Therefore, the request for Deprizine is not certified

**Dicopanol 5 mg/ml 150 ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants(for pain).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Mental Illness & Stress, Pain, Insomnia Treatment.

**Decision rationale:** CA MTUS guidelines do not discuss the issue in dispute and hence ODG have been consulted. As per ODG, Dicopanol (diphenhydramine) is sedating antihistamines have been suggested for sleep aids. Further guidelines indicate "Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance". The records provided do not adequately discuss the patient's insomnia and justification for diphenhydramine use which fits within guidelines. Therefore, the request for Dicopanol 5 mg/ml 150 ml is non-certified.