

<b>Case Number:</b>	CM14-0021002		
<b>Date Assigned:</b>	02/21/2014	<b>Date of Injury:</b>	09/04/2012
<b>Decision Date:</b>	07/25/2014	<b>UR Denial Date:</b>	12/25/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/07/2014

### 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. The expert reviewer is Board Certified in Occupational 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 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 patient is a 53-year-old female who has filed a claim for lumbar sprain associated with an industrial injury date of September 04, 2012. Review of progress notes indicates burning bilateral hand pain; burning radicular low back pain with muscle spasms, and numbness and tingling of the left lower extremity; burning bilateral foot pain; neck pain; right shoulder pain; stress; anxiety; insomnia; and depression. Findings include tenderness over bilateral hands, right shoulder, cervical, and lumbar region; decreased range of motion of bilateral hands, cervical and lumbar spine, right shoulder, and bilateral feet; positive impingement sign of the right shoulder; decreased myotomes of the upper and lower extremities, bilaterally; and decreased sensation of the bilateral lower extremities and right median nerve distribution. EMG/NCV dated February 11, 2013 showed mild left carpal tunnel syndrome. Treatment to date has included Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, muscle relaxants, Medrox patches, opioids, NSAIDs, chiropractic therapy, physical therapy, and arthroscopic repair of the right shoulder. Utilization review from December 25, 2013 denied the requests for Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex as there is no indication for use of an oral suspension, and certain components are not FDA-approved for use.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn 10mg/1ml susp 500ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate); Opioids, specific drug list, Tramadol Page(s): 50; 93.

**Decision rationale:** A search of online resources revealed that Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit. Tramadol is indicated for moderate to severe pain. CA MTUS Chronic Pain Medical Treatment Guidelines states that Glucosamine and Chondroitin Sulfate are recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Additionally, this drug has not been found by FDA to be safe and effective, and is not approved by the FDA. There is no indication of intolerance to conventional oral pain medications as patient is currently on NSAID and opioid therapy. Furthermore, there is no clear rationale identifying why a compound/oral suspension (as opposed to the evidence based guidelines supported and FDA approved non-compounded medication) is needed for this patient. Therefore, the request for Synapryn 10mg/1ml susp 500ml was not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Tabradol <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>.

**Decision rationale:** Tabradol is cyclobenzaprine hydrochloride with MSM in oral suspension. CA MTUS Chronic Pain Medical Treatment Guidelines state that cyclobenzaprine is a skeletal muscle relaxant and a CNS depressant that is recommended as a short-course therapy. The effect is greatest in the first 4 days of treatment. There is no documentation regarding intolerance to cyclobenzaprine in tablet form. In addition, Methylsulfonylmethane (MSM) is not FDA approved, and this medication is not recommended for long-term use. Therefore, the request for tabradol 1mg/ml oral susp 250ml was not medically necessary.

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

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Depirizine <http://www.drugs.com/pro/deprizine.html>.

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. There is no documentation regarding upper GI symptoms or diagnoses in this patient. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Deprizine 15mg/ml oral susp 250ml was not medically necessary.

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

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Dicopanol <http://www.drugs.com/cdi/diphenhydramine.html>.

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Dicopanol is diphenhydramine hydrochloride 5 mg/mL oral suspension. It is used to treat occasional sleeplessness and difficulty falling asleep. There is no documentation regarding sleep difficulties in this patient. In addition, there is no rationale provided for the medical necessity of an oral suspension. Therefore, the request for Dicopanol 5mg/ml oral susp 150ml was not medically necessary.

**Fanatrex 25mg/ml oral susp 420ml:** 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 Antiepilepsy drugs (AEDs) Page(s): 16-18.

**Decision rationale:** Fanatrex is gabapentin with other proprietary ingredients in oral suspension. As stated on pages 16-18 in the CA MTUS Chronic Pain Medical Treatment Guidelines, gabapentin is useful for treating diabetic painful neuropathy and postherpetic neuralgia, and is considered first-line for neuropathic pain. However, there is no rationale provided for the medical necessity of an oral suspension. There is no indication of intolerance to conventional oral pain medications as patient is currently on NSAID and opioid therapy. Therefore, the request for Fanatrex 25mg/ml oral suspension 420ml was not medically necessary.