

<b>Case Number:</b>	CM14-0190637		
<b>Date Assigned:</b>	11/24/2014	<b>Date of Injury:</b>	09/24/2013
<b>Decision Date:</b>	01/09/2015	<b>UR Denial Date:</b>	10/31/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/14/2014

### 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 Physical Medicine & 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 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 injured worker is a 48 year-old male with a date of injury of September 24, 2013. The patient's industrially related diagnoses include cervical radiculitis, derangement of joint of shoulder region, joint derangements of right elbow, lumbar sprain, pain in the joint involving lower leg, and cervical HNP. The disputed issues are Tabradol 1mg/ml oral suspension 250ml #1, Deprizine 15mg/ml oral suspension 250ml #1, and Synapryn 10mg/1ml oral suspension 500ml #1. A utilization review determination on 10/31/2014 had non-certified these requests. The stated rationale for the denial of the listed medications was: "There is no documentation of objective functional improvement despite the ongoing use of the current medication regimen. There was no evidence of spasticity or palpable muscle spasm upon physical examination that would warrant the need for a muscle relaxant. There was no evidence of cardiovascular disease or increased risk factors for gastrointestinal events that would warrant the need for a proton pump inhibitor. There is also no evidence of a failure to respond to nonopioid analgesics prior to the initiation of Synapryn 10mg. The medical necessity for the ongoing use of the current medication regimen has not been established. There is also no indication that the patient cannot safely swallow pills or capsules. The California MTUS Guidelines recommend weaning of opioid medication. Therefore, the current request is only partially certified for Synapryn 10mg/mL oral suspension 250 ml.

### 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 #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines criteria for use of opioids Page(s): 74-82.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-66 of 127.

**Decision rationale:** Regarding the request for Tabradol 1mg/ml oral suspension (cyclobenzaprine, methylsulfonylmethane and other proprietary ingredients), Chronic Pain Medical Treatment Guidelines support the use of nonsedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that cyclobenzaprine specifically is recommended for a short course of therapy. Within the medical records available for review, there was documentation that the medications do offer the injured worker temporary relief of pain, but there was no identification of a specific analgesic benefit or objective functional improvement as a result of the Tabradol. Furthermore, there was no rationale provided as to why an oral suspension is being prescribed instead of the tablets since there was no documentation that the injured worker had difficulty swallowing tablets. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. The documentation indicates that this medication has been prescribed with regularity since 4/28/2014. In light of these issues, the currently requested Tabradol 1mg/ml oral suspension 250 mL is not medically necessary.

**Deprizine 15mg/ml oral suspension 250ml #1:** 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 Page(s): 68-69 of 127.

**Decision rationale:** Regarding the request for Deprizine 15mg/ml oral suspension (ranitidine and other proprietary ingredients), California MTUS states that H2 receptor antagonists are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Criteria to determine if a patient is at risk for gastrointestinal events includes age over 65 years, history of GI bleeding or peptic ulcer, concurrent use of ASA, corticosteroids, and/or an anticoagulant, or high dose/multiple NSAID use. Within the medical records available for review, there was no indication that the injured worker had complaints of dyspepsia secondary to NSAID use or was at risk for gastrointestinal events with NSAID as outlined in the guidelines. Furthermore, there was no documentation that the injured worker was prescribed any oral NSAIDs at the time of this request. Without the use of NSAIDs, based on the guidelines, there is no indication for an H2 receptor antagonist for his industrial injury. In light of these issues, the currently requested Deprizine 15mg/ml oral suspension is not medically necessary.

**Synapryn 10mg/1ml oral suspension 500ml #1:** 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 Page(s): 75-80.

**Decision rationale:** Regarding the request for Synapryn 10mg/1mL oral suspension (tramadol, glucosamine, and other proprietary ingredients), Chronic Pain Medical Treatment Guidelines state that Tramadol is a synthetic opioid affecting the central nervous system. As of July 2014, the DEA changed the classification of Tramadol to a schedule IV controlled substance. Since Tramadol is an opioid, it is subject to the ongoing monitoring requirements recommended by the guidelines. Due to Tramadol's abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. Within the submitted medical records available for review, the treating physician indicated that the medications provided the injured worker temporary relief of pain and improved his ability to have restful sleep, but there was no specific documentation to support that Synapryn provided pain relief in terms of percent pain reduction or reduction in numeric rating scale, and no specific examples of functional improvement were provided. Furthermore, there was no discussion regarding possible aberrant drug-related behavior. There was no documentation of a signed opioid agreement, no urine drug screen results to assess for the use or the presence of illegal drugs, and no CURES report to confirm that the injured worker was only getting opioids from one practitioner. Lastly, there was no rationale provided as to why the injured worker is unable to take Tramadol in tablet form and requires the oral suspension. In the absence of such documentation, the currently requested Synapryn is not medically necessary. Although it is not medically necessary at this time, since it is an opioid, it should not be abruptly halted and the requesting provider should start a weaning schedule as he or she sees fit.