

<b>Case Number:</b>	CM14-0150815		
<b>Date Assigned:</b>	09/19/2014	<b>Date of Injury:</b>	08/09/2012
<b>Decision Date:</b>	10/17/2014	<b>UR Denial Date:</b>	08/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/16/2014

### 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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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:

This is a 54-year-old male with an 8/9/12 date of injury. The mechanism of injury was not included in the documentation. The patient was most recently seen by an orthopedic surgeon on 7/18/14, when the patient complained of a 6-7/10 radicular neck pain and an 8-9/10 radicular low back pain. Exam findings revealed a limited range of motion of the C-spine. The L-spine exam revealed an abnormal gait, a decreased range of motion, and a positive straight leg raise. The patient's diagnoses included C-spine pain, sprain of ligaments of C-spine and L-spine (rule out disc displacement), C-spine degenerative disc disease, and radiculopathy of C-spine and L-spine. The documents noted that the patient was prescribed Synapryn 10mg/1mL 500mL, 1 tsp TID, Dicopanol, Deprizine, Fanatrex, Ketoprofen, Cyclobenzaprine, and Tabradol. Treatment to date: medications, chiropractic care, localized intense neurostimulation therapy. An adverse determination was received on 8/20/14. No rationale was included in the documentation.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn 10 mg/ml, 500 ML 1 tsp TID (tramadol & glucosamine): 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 Opiates, Tramadol Page(s): 88-91; 113. Decision based on Non-MTUS Citation Official Disability

Guidelines (ODG) Pain Chapter Compound Drugs Other Medical Treatment Guideline or Medical Evidence: FDA (Synapryn)

**Decision rationale:** The California MTUS guidelines state that there should be ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects for patients taking narcotic analgesics. Satisfactory treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Furthermore, a search of online resources revealed that Synapryn, a compounding kit, contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine. This drug has not been found by the FDA to be safe and effective, and the FDA has not approved this labeling. Per Official Disability Guidelines (ODG), compound drugs are not recommended as first line therapy in medications that contain an over the counter ingredient, and glucosamine is over the counter and not regulated by the FDA. This patient complained of L-spine and C-spine pain according to the orthopedic surgery progress report dated 7/18/14. The patient was subsequently prescribed some compound medications, including Synapryn oral suspension. The documentation did not provide a 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. Furthermore, it was unclear if this patient had been on Synapryn previously, with any improvement in pain level or functional status. In addition, the FDA has not found Synapryn to be safe and effective. Therefore, the request for Synapryn 10 mg/ml, 500 ML 1 tsp TID (Tramadol & glucosamine), was not medically necessary.