

<b>Case Number:</b>	CM15-0029768		
<b>Date Assigned:</b>	03/20/2015	<b>Date of Injury:</b>	04/25/2011
<b>Decision Date:</b>	04/20/2015	<b>UR Denial Date:</b>	01/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/17/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: Internal Medicine

### 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 31 year old female who sustained an industrial injury on April 25, 2011 due to a fall. The injured worker was diagnosed as having cervical spine sprain/strain, cervical disc displacement herniated nucleus pulposus, cervical spine degenerative disc disease, cervical radiculopathy, thoracic spine pain, thoracic spine sprain/strain, thoracic spine herniated nucleus pulposus, low back pain, lumbar spine herniated nucleus pulposus, compression fracture of L2, and lumbar radiculopathy. Treatment and evaluation to date has included lumbar/cervical/thoracic spine MRIs, acupuncture, physical therapy, shockwave therapy, neurostimulation therapy, injections to the low back, braces, and medication. Approximately monthly progress notes from June 2014 to January 2015 were submitted. The reports are stereotyped and contain much of the same information from report to report. Synapryn, trabadol, deprizine, dicopanor, and fanatrex and several additional medications have been prescribed from June 2014 to January 2015. Currently, the injured worker complains of dull, achy neck pain and muscle spasms, mid back pain and muscle spasms, and lower back pain and muscles spasms. The primary treating physician's report dated January 8, 2015, noted the injured worker reported medications offered temporary relief of pain and improved ability to have restful sleep. Cervical spine examination revealed +2 tenderness to palpation at the suboccipital, scalene and sternocleidomastoid muscles, with tenderness to palpation over the spinous processes C2-C5. The thoracic spine examination revealed bilateral thoracic paraspinal muscle guarding with tenderness to palpation over the spinous process T4-T6. Lumbar spine examination revealed tenderness to palpation at the bilateral posterior superior iliac spines. Straight leg raise test was noted to be positive bilaterally.

Motor strength in the upper and lower extremities was decreased secondary to pain. There was normal sensation in the upper extremities and diminished sensation at the L4, L5, and S1 dermatomes in the right lower extremity. Current medications were listed as Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Capsaicin, Flurbiprofen, Menthol, Cyclobenzaprine, and Gabapentin. Work status was noted as modified work with limitations and restrictions from September 2014 to January 2015, and temporarily totally disabled in August 2014. A functional capacity evaluation was performed on 5/23/13. On 1/26/15, Utilization Review (UR) non-certified requests for synapryn 10mg/1ml oral suspension 500 ml, trabadol 1mg/ml oral suspension 250 ml, deprizine 15 mg/ml oral suspension 250 ml, dicopanol 5 mg/ml oral suspension 150 ml, fanatrex 25 mg/ml oral suspension 420 ml, and 1 functional capacity evaluation (FCE). UR cited the MTUS, ODG, and additional medical literature.

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

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

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids, glucosamine (and chondroitin sulfate) Page(s): 74-96, 50.

**Decision rationale:** Synapryn contains tramadol with glucosamine in oral suspension. The reason for combining these medications is not discussed in any physician report. Given that tramadol is generally an as-needed medication to be used as little as possible, and that glucosamine (assuming a valid indication) is to be taken regularly regardless of acute symptoms, the combination product is illogical and not indicated. Tramadol is prescribed without clear evidence of the considerations and expectations found in the MTUS and similar guidelines. Opioids are minimally indicated, if at all, for chronic back pain. The prescribing physician does not specifically address function with respect to prescribing opioids. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient "has failed a trial of non-opioid analgesics. The MTUS provides support for treating moderate arthritis pain, particularly knee OA, with glucosamine sulphate. Other forms of glucosamine are not supported by good medical evidence. The treating physician in this case has not provided evidence of the form of glucosamine in Synapryn, and that it is the form recommended in the MTUS and supported by the best medical evidence. Should there be any indication for glucosamine in this case, it must be given as a single agent apart from other analgesics, particularly analgesics like tramadol which are habituating. Synapryn is not medically necessary based on the MTUS, lack of good medical evidence, and lack of a treatment plan for chronic opioid therapy consistent with the MTUS.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation

University of Michigan Health System. Gastroesophageal reflux disease (GERD). Ann Arbor (MI): University of Michigan Health System; 2007 Jan. 10p.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

**Decision rationale:** The MTUS recommends co-therapy of non-steroidal anti-inflammatory drugs (NSAIDs) with a proton pump inhibitor (PPI) in patients who are determined to be at intermediate or high risk of a gastrointestinal (GI) event. There is no recommendation for H2 receptor antagonists for gastric protection from NSAID use. A H2-receptor antagonist may be considered for treatment of dyspepsia secondary to NSAID therapy. Deprizine is ranitidine in an oral suspension. Ranitidine is prescribed without any rationale provided. The documentation indicates that flurbiprofen, a NSAID, is also prescribed. If ranitidine is prescribed as cotherapy with an NSAID, ranitidine is not the best drug. Note the MTUS recommendations cited. There was no documentation of dyspepsia. There are no medical reports which describe signs and symptoms of possible GI disease. There is no examination of the abdomen on record. Cotherapy with an NSAID is not indicated in patients other than those at high risk. No reports describe specific risk factors to be present in this case. Due to lack of indication, deprizine is not medically necessary.

**Dicopanol (Diphenhydramine) 5mg/ml oral suspension 420mg:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

**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 treatment.

**Decision rationale:** Dicopanol contains diphenhydramine and other unnamed ingredients. Medical necessity cannot be determined for unspecified compounds, and unpublished ingredients cannot be assumed to be safe or effective. Dicopanol is not medically necessary on this basis alone. The reason for prescription of dicopanol was not specifically stated, but may be due to sleep disturbance as the treating physician notes that medications improve ability to have restful sleep. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Note the Official Disability Guidelines citation above. That citation also states that antihistamines are not indicated for long term use as tolerance develops quickly, and that there are many, significant side effects. Dicopanol is not medically necessary based on lack of a sufficient analysis of the patient's condition, the ODG citation, and lack of information provided about the ingredients.

**Fanatrex (Gabapentin) 25mg/ml oral suspension 420mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-convulsants Page(s): 16-22.

**Decision rationale:** Fanatrex is a formulation of gabapentin in oral suspension. Per the MTUS, antiepilepsy drugs (AEDs) are recommended for neuropathic pain due to nerve damage. Gabapentin has been shown to be effective for treatment of diabetic neuropathy and postherpetic neuralgia and has been considered a first line treatment for neuropathic pain. The MTUS notes the lack of evidence for treatment of radiculopathy. There was no discussion of neuropathy for this injured worker, and current diagnoses include lumbar radiculopathy. Fanatrex has been prescribed for at least 6 months without documentation of functional improvement. Although work status was changed from temporarily totally disabled to modified work with restrictions in September 2014, there was no documentation that this was the result of any specific intervention. There was no documentation of improvement in activities of daily living, no decrease in medication use and no decrease in frequency of office visits. Due to lack of indication and lack of functional improvement, the request for fanatrex is not medically necessary.

**Functional Capacity Evaluation (FCE):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines- Fitness for Duty.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) fitness for duty chapter, functional capacity evaluation.

**Decision rationale:** Per the ODG, functional capacity evaluation (FCE) is recommended prior to admission to a Work Hardening (WH) Program, with preference for assessments tailored to a specific task or job. FCE is not recommend for routine use as part of occupational rehab or screening, or generic assessments in which the question is whether someone can do any type of job generally. The documentation did not indicate that admission to a work hardening program was anticipated. A functional capacity evaluation was noted to have been performed on 5/23/13, and there was no documentation of why another FCE was requested. Due to lack of indication, the request for functional capacity evaluation is not medically necessary.