

<b>Case Number:</b>	CM14-0079671		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	10/03/2013
<b>Decision Date:</b>	09/12/2014	<b>UR Denial Date:</b>	05/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/30/2014

### 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 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 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 male patient with the date of injury of October 3, 2013. A Utilization Review was performed on May 27, 2014 and recommended non-certification of compounded Ketoprofen 20% 120gms, compounded Cyclophene 5% 120gms, Synapryn 10mg (10mg/1ml) oral suspension 500ml, Tabradol 1mg/ml oral suspension 250ml, Deprizine 15mg/ml oral suspension 250ml, Dicopanol (diphenhydramine) 5mg/ml oral suspension 150ml, and Fanatrex (gabapentin) 25mg/ml oral suspension 420ml. A Progress Report dated May 6, 2014 identifies Subjective Complaints of headaches located mostly on the left side, radicular neck pain and muscle spasms, right shoulder pain, and radicular low back pain and muscle spasms. Objective Findings identify tender occiputs, trapezius, splenius, scalene, and SCM muscles, with stiffness. Decreased ROM. Cervical distraction and cervical compression positive bilaterally. Tender trapezius, levator scapula, and rhomboid muscles, as well as at the AC joint and biceps tendon. Decreased right shoulder ROM. Neer's impingement sign and Kennedy Hawkins are positive. Sensation to pinprick and light touch is decreased. Motor strength is 4/5. Diagnoses identify status post blunt head trauma, cervicgia, radiculopathy cervical region, right shoulder - joint derangement unspecified, low back pain, and radiculopathy lumbar region. Treatment Plan is to continue current treatment.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compounded Ketoprofen 20% 120 gms: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (Effective July 18, 2009) Page(s): 111-113.

**Decision rationale:** Regarding request for compounded Ketoprofen, Chronic Pain Medical Treatment Guidelines state that any compounded product that contains at least one drug or drug class that is not recommended is not recommended. The Guidelines go on to state that Ketoprofen is not currently FDA approved for a topical application. As such, the currently requested compounded Ketoprofen is not medically necessary.

**Compounded Cyclophene 5% 120 gms:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Muscle Relaxants Page(s): 113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (Effective July 18, 2009) Page(s): 111-113.

**Decision rationale:** Regarding the request for compounded Cyclophene, Chronic Pain Medical Treatment Guidelines state that topical muscle relaxants are not recommended. They go on to state that there is no evidence for the use of any muscle relaxants as a topical product. Therefore, in the absence of guideline support for topical muscle relaxants, the currently requested compounded Cyclophene is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 81.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (Effective July 18, 2009) Page(s): 50 and 75-79. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:<http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>.

**Decision rationale:** Regarding the request for Synapryn, Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine - compounding kit. Regarding Tramadol, California Pain Medical Treatment Guidelines state that Tramadol is a short acting opiate pain medication. Due to high 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. Regarding Glucosamine, California Pain Medical Treatment Guidelines state it is recommended as an option, given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no indication that Tramadol is improving the patient's function (in terms of

specific objective functional improvement) or pain (in terms of reduced NRS, or percent reduction in pain), no documentation regarding side effects, and no discussion regarding aberrant use. In addition, there is no documentation of moderate arthritis pain. In the absence of such documentation, the currently requested Synapryn is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (Effective July 18, 2009) Page(s): 63-66. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:  
<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5d19ef8b-eef3-4d52-95f5-929765ca6dc7>.

**Decision rationale:** Regarding the request for Tabradol, Tabradol contains cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension with MSM - compounding kit. Regarding cyclobenzaprine, Chronic Pain Medical Treatment Guidelines support the use of non-sedating 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 documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the cyclobenzaprine. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. In the absence of such documentation, the currently requested Tabradol is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and cardiovascular risks Page(s): 68 and 69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (Effective July 18, 2009) Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Proton Pump Inhibitors (PPIs) Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/pro/deprizine.html>.

**Decision rationale:** Regarding the request for Deprizine, Deprizine contains active and inactive bulk materials to compound a ranitidine hydrochloride oral suspension. California MTUS states that proton pump inhibitors are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Within the documentation available for review, there is no indication that the patient has complaints of dyspepsia secondary to NSAID use, a risk for gastrointestinal events with NSAID use, or another indication for this medication. In light of the above issues, the currently requested Deprizine is not medically necessary.

**Dicopanor (diphenhydramine) 25 mg/ml oral suspension 150 ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness and Stress, Insomnia.

**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 Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/pro/dicopanor.html>.

**Decision rationale:** Regarding the request for Dicopanor, Dicopanor contains active and inactive bulk materials to compound a diphenhydramine hydrochloride oral suspension. California MTUS guidelines are silent. ODG states sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there are no subjective complaints of insomnia, no discussion regarding how frequently the insomnia complaints occur or how long they have been occurring, no statement indicating what behavioral treatments have been attempted for the condition of insomnia, and no statement indicating how the patient has responded to treatment with Dicopanor. Finally, there is no indication that Dicopanor is being used for short term use as recommended by guidelines. In the absence of such documentation, the currently requested Dicopanor is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin, Anti-Epileptic Page(s): 113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (Effective July 18, 2009) Page(s): 16-21 of 127. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/pro/fanatrex.html>.

**Decision rationale:** Regarding the request for Fanatrex, Fanatrex contains active and inactive bulk materials to prepare 420 mL of a gabapentin oral suspension containing 25 mg/mL gabapentin. Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that after initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no discussion

regarding side effects from this medication. In the absence of such documentation, the currently requested Fanatrex is not medically necessary.