

<b>Case Number:</b>	CM15-0123466		
<b>Date Assigned:</b>	07/07/2015	<b>Date of Injury:</b>	10/04/2014
<b>Decision Date:</b>	08/19/2015	<b>UR Denial Date:</b>	06/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/26/2015

### 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: New York  
 Certification(s)/Specialty: Pediatrics, 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 19 year old female, who sustained an industrial injury on 10/04/2014. She reported an injury to her left wrist. Diagnoses included left wrist pain rule out carpal tunnel syndrome and rule out left wrist De Quervain's tenosynovitis. According to a comprehensive primary treating physician report dated 01/20/2015, the injured worker complained of burning left wrist pain and muscle spasms. Her pain was described as moderate to severe. Pain was rated 7 on a scale of 1-10. She also complained of weakness, numbness, tingling and pain radiating to the hands and fingers. She denied any history of heart disease, lung disease, liver disease, kidney disease, thyroid disease, high blood pressure, stomach problems or cancer. She was prescribed Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine and Ketoprofen cream. She was temporarily totally disabled. Electromyography and nerve conduction velocity study report dated 05/04/2015 noted normal results. According to a progress report dated 05/21/2015, the injured worker complained of burning left wrist pain and muscle spasms. Her pain was described as constant, moderate to severe. Pain was rated 5-6 on a scale of 1-10. She also complained of weakness, numbness, tingling and pain radiating to the hand and fingers. Symptoms persisted but the medications offered her temporary relief of pain and improved her ability to have a restful sleep. She denied any problems with the medications. The treatment plan included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine and Ketoprofen cream and acupuncture and shockwave therapy for the left wrist. She remained temporarily totally disabled. Currently under review is the request for retro Synapryn 10mg/ml oral suspension 500ml, retro Tabradol 1mg/ml oral suspension 250ml, retro Deprizine 5mg/ml oral suspension 250ml and retro Dicopanol 5mg/ml oral suspension.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Retro Synapryn 10mg/ml oral suspension 500ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical compounding medications Page(s): 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic) - Compound drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain, Opioids Page(s): 9, 78-94.

**Decision rationale:** According to the California MTUS, Synapryn oral suspension (Tramadol hydrochloride) is a synthetic opioid which affects the central nervous system and is indicated for the treatment of moderate to severe pain. Per CA MTUS Guidelines, certain criteria need to be followed, including an ongoing review and documentation of pain relief and functional status, appropriate medication use, and side effects. Pain assessment should include current pain: last reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid, and the duration of pain relief. According to the medical records, there has been no documentation of the medication's analgesic effectiveness or functional improvement, and no clear documentation that the patient has responded to ongoing opioid therapy. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Medical necessity for the requested is not established. The requested treatment is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical compounding medications Page(s): 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic) - Compound drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management, Muscle Relaxants Page(s): 9, 63-64.

**Decision rationale:** According to MTUS Guidelines, Tabradol (Cyclobenzaprine) oral suspension is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. Muscle relaxants are not considered any more effective than non-steroidal anti-inflammatory medications alone. In this case, despite long term use, the injured worker continued to complain of muscle spasms. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. The request is not medically necessary.

**Retro Deprizine 5mg/ml oral suspension 250ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical compounding medications Page(s): 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic) - Compound drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal Anti-inflammatory Drugs Page(s): 68.

**Decision rationale:** MTUS Guidelines state risks for gastrointestinal events include: age > 65 years, history of peptic ulcer, gastrointestinal bleeding or perforation, concurrent use of aspirin, corticosteroids and and/or an anticoagulant or high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Deprizine (Ranitidine) oral suspension is a histamine 2 blocker used to treat and prevent ulcers, and also treats gastro-esophageal reflux (GERD). Ranitidine works by blocking the effects of histamine on the receptor site known as H2. Proton Pump Inhibitors (PPI's) are prescribed to prevent and treat ulcers in the duodenum (where most ulcers develop) and the stomach. The injured worker was not documented as having peptic ulcers, gastritis and gastroesophageal reflux disease. Documentation did not show any complaints of gastrointestinal symptoms. Medical necessity of the Deprizine (Ranitidine) oral suspension has not been established. The requested medication is not medically necessary.

**Retro Dicopanол 5mg/ml oral suspension: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical compounding medications Page(s): 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic) - Compound drugs.

**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:** Dicopanол, the oral suspension form of Diphenhydramine, is an antihistamine that is used for the temporary relief of seasonal and perennial allergy symptoms. The medication is sedating and has been used for short-term treatment of insomnia. Official Disability Guidelines recommend that treatment of insomnia be based on the etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed and include sleep onset, sleep maintenance, sleep quality and next day functioning. Guidelines state that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine (Benadryl, over the counter in U.S.) Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. This RCT determined that diphenhydramine has been shown to build tolerance against its sedation effectiveness very quickly, with placebo-like results after a third day of use. In this case, Dicopanол was prescribed for insomnia. There was no discussion regarding sleep onset, sleep maintenance, sleep quality and next-day functioning. Guidelines do not recommend Diphenhydramine. Medical necessity for the requested treatment was not established. The requested treatment is not medically necessary.