

<b>Case Number:</b>	CM15-0105392		
<b>Date Assigned:</b>	06/09/2015	<b>Date of Injury:</b>	08/24/2012
<b>Decision Date:</b>	07/13/2015	<b>UR Denial Date:</b>	05/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/01/2015

### 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: Anesthesiology

### 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 53 year old female, who sustained an industrial injury on August 24, 2012. The mechanism of injury was a slip backwards. The injured worker has been treated for neck, shoulder, back and wrist complaints. The diagnoses have included cervical sprain/strain, cervical radiculopathy, right wrist sprain/strain, brachial neuritis, calcifying tendinitis of the shoulder, shoulder rotator cuff syndrome, joint pain of the forearm, lumbar sprain/strain, lumbar disc displacement with radiculopathy, lumbar facet syndrome, cervicogenic headaches, anxiety and depression. Treatment to date has included medications, radiological studies, MRI and injections. Current documentation dated April 7, 2015 notes that the injured worker reported constant neck pain radiating to the head with intermittent headaches. The injured worker also noted constant right upper extremity pain with associated weakness and grip loss and mid and lower back pain with radiation to the right lower extremity. Examination of the cervical spine revealed tenderness and spasms about the cervical spine and right trapezius muscles. Range of motion was noted to be restricted. There was also weakness noted in the right shoulder with abduction and flexion. Sensation to pinprick was decreased about the right forearm. The treating physician's plan of care included a request for the medications Synapryn 10 mg/1 ml 500 ml, Tabradol 1mg/ml 250 ml, Deprizine 15 mg/ml 250 ml, Dicopanol 5 mg/ml 150 ml and Fanatrex 25 mg/ml 420 ml.

### IMR ISSUES, DECISIONS AND RATIONALES

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

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use, Opioids for chronic pain Page(s): 76-81.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 93-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Opioids.

**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. An oral suspension is a suspension consisting of undissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. Evidence-based guidelines and peer-reviewed medical literature do not address the use of medications in oral suspension form. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Medical necessity for the requested Synapryn 10mg/ml oral suspension has not been established. Of note, discontinuation of an opioid analgesic requires a taper to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Tabradol 1mg/ml, 250ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 63.

**Decision rationale:** According to the reviewed literature, 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. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than non-steroidal anti-inflammatory medications alone. In this case, there are no muscle spasms documented on physical exam. There is no documentation of functional improvement from any previous use of this medication. Tabradol oral suspension is a suspension consisting of undissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. Evidence-based guidelines

and peer-reviewed medical literature do not address the use of medications in oral suspension form. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Based on the currently available information, the medical necessity for Tabradol 1mg/ml oral suspension has not been established. The requested medication is not medically necessary.

**Deprizine 15mg/ml, 250ml:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine.

**Decision rationale:** Deprizine (Ranitidine) oral suspension is a histamine blocker and antacid used to treat peptic ulcers, gastritis and 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. Deprizine oral suspension is a suspension consisting of undissolved particles of one or more medicinal agents mixed with a liquid vehicle for oral administration. Evidence-based guidelines and peer-reviewed medical literature do not address the use of medications in oral suspension form. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Medical necessity of the Deprizine (Ranitidine) oral suspension has not been established. The requested medication is not medically necessary.

**Dicopanol (Diphenhydramine) 5mg/ml, 150ml:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Sedative hypnotics.

**Decision rationale:** Dicopanol, 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. There is no documentation indicating the patient has any history of insomnia. Dicopanol is generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there was no documentation in the medical records of any conditions that would

preclude the use of medications in their pill/tablet form. Medical necessity for the requested oral suspension medication was not established. The requested medication was not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs Page(s): 18-19.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Gabapentin.

**Decision rationale:** According to the CA MTUS (2009) and ODG, Fanatrex Oral Suspension (Gabapentin) is an anti-epilepsy drug, which has been considered a first-line treatment for neuropathic pain. Oral suspensions of medications are generally for use in patients for whom taking the pill/tablet form of the medication is either impractical or unsafe. In this case, there is no documentation in the medical records of any conditions that would preclude the use of medications in their pill/tablet form. Medical necessity for the requested medication, Fanatrex 25mg/ml oral suspension, has not been established. The requested medication is not medically necessary.