

<b>Case Number:</b>	CM15-0114285		
<b>Date Assigned:</b>	06/22/2015	<b>Date of Injury:</b>	10/02/2014
<b>Decision Date:</b>	07/29/2015	<b>UR Denial Date:</b>	05/26/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/12/2015

### 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 56 year old male, who sustained an industrial injury on 10/2/2014. He reported slipping and falling onto his right side, injuring his shoulder. Diagnoses have included right shoulder sprain/strain, right shoulder internal derangement, right elbow sprain/strain and right hip sprain/strain. Treatment to date has included physical therapy and medication. According to the progress report dated 5/5/2015, the injured worker complained of right shoulder pain rated 3-4/10 on the visual analog scale (VAS) without medication and 0/10 with medication. The injured worker complained of right elbow pain rated 5/10 without medication and 1-2/10 with medication. Exam of the right shoulder revealed reduced range of motion and tenderness to palpation. Exam of the right elbow revealed tenderness to palpation and decreased range of motion due to pain. There was also tenderness to palpation over the right hip. Authorization was requested for Fanatrex oral suspension, Cyclobenzaprine cream, Dicoprofen oral suspension, Synapryn suspension, Tabradol oral suspension, Ketoprofen cream and Depizine oral suspension.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fanatrex 25mg/ml oral suspension 420ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov-Fanatrex>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 17-19, 49. 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.

**Cyclobenzaprine 5% cream 110gms:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Non Steroidal Anti Inflammatory Drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. In this case, the requested topical agent is a muscle relaxant, Cyclobenzaprine 5% Cream. Cyclobenzaprine is not recommended as a topical agent, per CA MTUS guidelines. Medical necessity for the requested topical medications is not established. The requested topical cream is not medically necessary.

**Dicopanol 5mg/ml oral suspension quantity 150ml:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Compound Drugs. Decision based on Non-MTUS Citation Official Disability Guidelines, Co-Pack drugs.

**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:** Dicopanor, 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. Dicopanor 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 is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Co-pack drugs; compound drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for the treatment of chronic pain Page(s): 93-96.

**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. 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 oral suspension 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, Co-Pack Drugs; Compound Drugs.

**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 un-dissolved 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 request for Tabradol 1mg/ml oral suspension is not medically necessary and has not been established.

**Ketoprofen 20% cream quantity 167gms:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; Non Steroidal Anti Inflammatory Drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The requested topical analgesic compound for this patient is Ketoprofen 20% cream. Ketoprofen is not currently FDA approved for a topical application, and has an extremely high incidence of photo-contact dermatitis. Medical necessity for the requested topical medication has not been established. The requested topical cream is not medically necessary.

**Deprizine 15mg/ml oral suspension 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, Co-Packs drugs; Compound Drugs.

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

**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.