

<b>Case Number:</b>	CM15-0091202		
<b>Date Assigned:</b>	05/15/2015	<b>Date of Injury:</b>	03/07/2013
<b>Decision Date:</b>	07/17/2015	<b>UR Denial Date:</b>	04/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/12/2015

### 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 45-year-old, male who sustained a work related injury on 3/7/13. The diagnoses have included low back pain, lumbar herniated nucleus pulposus and lower extremity radiculitis. Treatments have included oral medications, pain cream, Terocin patches, acupuncture, physical therapy, chiropractic treatments, shockwave therapy and ice therapy. In the PR-2 dated 4/2/15, the injured worker complains of lower back pain with spasms. He describes the pain as burning, constant and moderate to severe. He has pain that radiates down both legs with associated numbness and tingling. He rates the pain level a 6/10. He complains of weakness in his left leg. He states the pain is made worse by daily activities. He has tenderness to palpation over lower lumbar spine with paravertebral spasms. He has sciatic notch tenderness. He has decreased range of motion in lower back. He has a positive straight leg raise with left leg. The treatment plan includes requests for refills of oral medications and pain cream.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Compound Medication: Capsaicin, Flurbiprofen, Menthol, Cyclobenzaprine, Gabapentin:**  
Upheld

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

**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 compounded medication contains Capsaicin, Flurbiprofen, Menthol, Cyclobenzaprine, and Gabapentin. In this case, there is no documentation of intolerance to other previous oral medications. MTUS guidelines state that Flurbiprofen, Gabapentin, and Cyclobenzaprine are not recommended for topical applications. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. Medical necessity for this topical analgesic is not established. The requested topical analgesic is not medically necessary.

**Deprozone 15mg/ml Oral 250ml:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Up-To-Date, Ranitidine.

**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. They also counter the various problems that occur when stomach acid escapes into the esophagus, which if it happens on a regular basis, is GERD. In most trials, the PPIs have proved to be superior to the H2 blockers. 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. In addition, there is no documentation indicating that this patient has had any GI symptoms or risk factors. GI risk factors include age >65, history of peptic ulcer, GI bleeding, or perforation; concurrent use of aspirin, corticosteroids, and/or anticoagulants, or high dose/multiple NSAIDs. Medical necessity of the Deprizine (Ranitidine) oral suspension is not established. The requested medication is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drug. Decision based on Non-MTUS Citation [www.ddrugs.com/pro/fanatrex.html](http://www.ddrugs.com/pro/fanatrex.html).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) AEDs.

**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, the patient has neuropathic pain but 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.

**Synapryn 10mg/ml oral 250ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for the treatment of chronic pain Page(s): 91-97. 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.

**Lumbar Epidural Steroid Injection:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injection (ESIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines ESIs Page(s): 46.

**Decision rationale:** Epidural steroid injections (ESIs) are recommended as an option for treatment of radicular pain (defined as pain in a dermatomal distribution with corroborative findings of radiculopathy). Most current guidelines recommend no more than 2 ESI injections. Research has shown that, on average, less than two injections are required for a successful ESI outcome. ESIs can offer short-term pain relief and use should be in conjunction with other rehab efforts. The purpose of ESIs is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months. The CA MTUS guidelines state radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electro-diagnostic testing. The patient must be initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). In this case, there is evidence of radiculopathy on exam however; there are no imaging reports provided to support pathology in the lumbar spine that correlates with the physical exam findings. In addition, there is a lack of documentation of the conservative care that has been if failed to improve the current symptoms. Medical necessity for the requested left lumbar ESI has not been established. The requested lumbar ESI is not medically necessary.

