

<b>Case Number:</b>	CM13-0060931		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	05/15/2013
<b>Decision Date:</b>	05/16/2014	<b>UR Denial Date:</b>	11/18/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/04/2013

### 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 Occupational Medicine and is licensed to practice in California and Oklahoma. 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:

The patient is a 35 year old male who was injured on 05/15/2013 when he slipped on the floor and fell backwards, landing on his lower back. The patient underwent a cyst removal in the back in 2008. The patient's medications as of 02/03/2014 include Norco, Omeprazole and Naproxen. Urine drug screen dated 09/26/2013 did not detect prescribed medications. Diagnostic studies reviewed include a Polysomnography dated 09/01/2013 demonstrated abnormal sleep architecture with increased stage 2 and slightly decreased stage REM sleep. The patient's sleep efficiency and sleep maintenance were within slightly reduced indicating the patient had difficulty initiating and maintaining sleep. The patient's PLM's were elevated, indicating discomfort and stress during their sleep time. The patient demonstrated excessive and loud snoring which was noted as heard outside the patient's room. MRI of the lumbar spine dated 08/06/2013 revealed L5-S1 degenerative disk disease with a small central disk protrusion, perhaps, 2mm. MRI of the sacrococcygeal spine dated 06/26/2013 did not reveal any acute foreign bodies or bony destructive processes are identified. MRI of the lumbosacral spine dated 06/07/2013 demonstrated splinting of the spine to the right suggesting muscle spasm; clinical correlation will be necessary. According to the Letter of Medical Necessity dated 12/19/2013 and 12/30/2013, the following medications were dispensed; compounded Ketoprofen, compounded Cyclophene; Dicopanol; Deprizine; Synapryn; Tabradol, Fanatrex and Tabradol. There is no documentation to support whether or not the patient was consistently taking medications as prescribed nor is there any documented benefit of taking the prescribed medications. PR2 dated 12/27/2013 indicated the patient had complaints of burning, radicular low back pain and muscle spasms, 5-6/10, radiating into the coccyx, both buttocks and in the bottom of the feet, associated with numbness and tingling of the bilateral lower extremities, constant, moderate to severe. He denied any bowel or bladder problems. He received an injection to his lower back which

benefitted him for about 5 days after which period the pain began recurring and he began experiencing headaches after injection. The patient stated that the symptoms persisted but the medications do offer him temporary relief of pain and improved his ability to have restful sleep. He denied any problems with the medications. The pain was also alleviated by activity restrictions. Objective findings on exam revealed an antalgic gait. He was able to heel-toe walk with pain. He could squat to 15% and myelocyst noted. The skin was macerated; clear exudates were derived from the cyst with intense odor. There was tenderness at the coccygeal area. He had decreased range of motion; tripod, Flip and Laseque's Differential positive bilaterally. His sensation was diminished bilaterally; motor strength was decreased bilaterally in lower extremities. The patient was diagnosed with low back pain, status post fracture of the coccyx, and headaches. The patient was advised to stop taking the medications if he had any problems with them. Medications, especially oral medications are to be monitored closely for effectiveness and possible dependency therefore periodic UA toxicological evaluation shall be performed. There were medications prescribed, physical therapy and chiropractic therapy recommended. PR2 dated 10/30/2013 documented the patient to have complaints of burning, radicular low back pain and muscle spasms, 5-6/10, radiating into the coccyx, both buttocks and in the bottom of the feet, associated with numbness and tingling of the bilateral lower extremities, constant, moderate to severe. He denied any bowel or bladder problems. The patient stated he did not receive the medications. The patient stated that the pain was alleviated with medications, rest and activity restriction. The patient was diagnosed with low back pain and status post fracture of the coccyx. The usage of the medications has been explained to the patient. The patient was advised to stop taking the medications if began to have any problems. The recommendation was for the patient to undergo an EMG/NCV study of the right and left lower extremities. It was also recommended the patient be seen by a pain management specialist for a consultation regarding epidural steroid injections for the lumbar spine. The patient was prescribed medication, physical therapy and chiropractic therapy.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**SYNAPRYN 10MG/ML 500ML:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids/Opioids Specific Drug List Page(s): 82-83, 93-94.

**Decision rationale:** According to the medical literature, Synapryn is a oral suspension containing Tramadol. According to the California MTUS, Tramadol (Ultram<sup>®</sup>) is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic, it is indicated for moderate to severe pain. According to the PR2 dated 12/27/2013, the patient complains of 5-6/10 pain. The medical records do not establish clinically significant pain and functional improvement with medication. In addition, there are no details regarding use of non-opioid and non-pharmacologic means of addressing pain. Furthermore, the medical records do not establish this patient is unable to tolerate standard oral medications. The medical necessity of an oral suspension is not established. However the provider has justified in the medical records the need for this medication after seeing the patient face to face citing non specific published studies. Despite a variance from the guidelines, this medication is necessary.

**TABRADOL 1MG/ML, 250ML: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril®), Muscle Relaxants (For Pain) Page(s): 41, 63.

**Decision rationale:** Trabadol is a suspension formulation containing cyclobenzaprine hydrochloride as active ingredient. According to the guidelines, Cyclobenzaprine is recommended as a short course of therapy only. Muscle relaxants should be considered as a second-line option to treat exacerbations. The medical records do not establish this patient has presented with any acute exacerbation of chronic pain. In addition, the medical records do not document any attempts with self-directed care such as would include heat/ice, range of motion/stretching exercises, and such. Furthermore, the medical records do not establish the patient is unable to tolerate standard oral medications. However, the provider has stated that patient has failed a trial of NSAIDS, so this would be second line treatment as per the guidelines. Despite a variance from the guidelines, this medication is necessary.

**DEPRIZINE 15MG/ML, 250ML: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** The medical records reviewed do not document any gastrointestinal complaints. According to the medical literature, Deprizine is an oral suspension containing ranitidine (zantac). According to the California MTUS guidelines, antacids are recommended for patients at risk for gastrointestinal events. Determining factors are 1) age over 65 years, 2) history of peptic ulcer, GI bleeding or perforation, 3) concurrent use of ASA, corticosteroids, and/or an anticoagulants, or 4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). The medical records do not establish any of these risk factors are present in the case of this patient. The medical records do not establish this patient is at notable risk for GI events. All other agents should be considered second-line therapy. Furthermore, the medical records do not establish medical necessity for oral suspension formulation. However, the provider notes the justification of this medication stating that NSAIDS have a black box warning regarding GI irritation. Deprizine is acceptable and medically necessary.

**DICOPANOL 5MG/ML, 150ML: Overturned**

**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) PAIN, INSOMNIA TREATMENT

**Decision rationale:** Dicophanol is an oral suspension, active Ingredient: diphenhydramine hydrochloride, manufactured by [REDACTED] pharmaceuticals. Diphenhydramine is an antihistamine, it is used to relieve red, irritated, itchy, watery eyes; sneezing; and runny nose caused by hay fever, allergies, or the common cold. According to ODG, sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. The provider notes that this medication is being used for insomnia. It is a safe and low cost intervention and medically necessary.

**FANATREX 25ML/ML, 420ML:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy Drugs (AEDS) Page(s): 16, 18.

**Decision rationale:** Fanatrex is an oral suspension, active Ingredient: Gabapentin, manufactured by [REDACTED] pharmaceuticals. According to the California MTUS guidelines, an anti-epilepsy drug (AED), such as Gabapentin, is recommended for neuropathic pain (pain due to nerve damage). Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. The medical records do not establish the patient has neuropathic pain. There lacks specific subjective complaints with correlative objective clinical findings, and/or corroborative electrodiagnostic evidence to establish active neuropathy is present. Furthermore, the medical records do not establish the patient is unable to tolerate standard oral medications, the medical necessity for an oral suspension is not established. However, the provider notes that this is being used in leue of opioids which carry substancial risks. Therefore Fanatrex is medically necessary.