

<b>Case Number:</b>	CM14-0076180		
<b>Date Assigned:</b>	07/21/2014	<b>Date of Injury:</b>	04/25/2013
<b>Decision Date:</b>	09/17/2014	<b>UR Denial Date:</b>	05/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/23/2014

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Florida. 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 injured worker is a 34-year-old male who reported an injury on 05/25/2013, reportedly sustained injuries to his lower back and coccyx. The injured worker slipped on a patch of glue like liquid, and fell backwards, landing on his buttocks, hitting his lower back on the first step of a set of stairs which he was descending. The injured worker's treatment history included x-rays, MRI, medications, and urine drug screen. The injured worker was evaluated on 05/15/2014 and it was documented that the injured worker complained of low back pain that was sharp, stabbing, radicular lower back pain. He rated the pain at 7/10 on a pain analog scale. His pain was described as constant and severe. It was associated with radiating pain down to the sacro-coccygeal region and to the bilateral lower extremities with numbness and tingling. The pain was aggravated by prolonged positioning, including sitting, standing, walking, bending, rising from a sitting position, ascending or descending stairs and stooping. His pain was also aggravated by activities of daily living such as getting dressed and performing personal hygiene. The injured worker complained of pain and pressure in the left inguinal/testicular region. The provider noted the injured worker stated the symptoms persist but the medications do offer him temporary relief of pain and improve his ability to have restful sleep. He denied any problems with the medications. The pain was also alleviated by activity restrictions. Physical examination of the lumbar spine revealed the injured worker was able to heel to toe walk, however, with pain in his lower back. The injured worker was able to squat to approximately 10% of normal due to the pain in the lower back. There was +2 tenderness to palpation at the paralumbar, quadratus lumborum muscles, and over the lumbosacral junction. Motion of the lumbar spine into the knees, extension 20 degrees, left/right lateral flexion was 15 degrees, left rotation 10 degrees and right rotation 20 degrees. Leg raise right/left was positive at 60 degrees. Laseque's differential right/left was positive. Left inguinal/testicular examination, there was tenderness to palpation at

the left inguinal canal. There was no documentation of tenderness at the epididymis. L2, L3, L4, L5 and S1 myotomes were decreased in the left lower extremities secondary to pain. The reflexes are 1+ in the left lower extremities and 2+ in the right lower extremities. Medications included Ketoprofen 20% gel, Cyclophene 5% gel, Synapryn10mg, Tabradol 1mg, Fenatrex 25 mg, and Deprizine 15 mg.

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

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

**Ketoprofen 20% in PLO Gel 120 gms: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic Page(s): 112-113.

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

**Decision rationale:** The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Topical Analgesics, pages 111-113. The Expert Reviewer's decision rationale: California (MTUS) Chronic Pain Medical Guidelines state "topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate." Non-steroidal anti-inflammatory agents (NSAIDs) efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. MTUS also states, "Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The documents submitted did not lack evidence of outcome measurements of conservative care such as, physical therapy, pain medication management and home exercise regimen. In addition the request lacked duration, frequency and location where topical is supposed to be applied on injured worker. Given the above, the request is not supported by the guidelines noting the safety or efficacy of this medication. The request for retrospective for medication Ketoprofen 20% in PLO Gel 120gms is not medically necessary.

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

**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, criteria for use, Tramadol Page(s): 78, 113.

**Decision rationale:** The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Opioids, Criteria for use, Tramadol, pages 78, 113. The Expert Reviewer's decision rationale: The request for Synapryn 10 mg/1ml oral suspension 500ml is medically necessary. The California Medical Treatment Utilization Schedule (MTUS) guidelines do not recommend Tramadol as a first-line oral analgesic. The criteria for use for ongoing- management of opioids include ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. There was lack of evidence of opioid medication management and average pain, intensity of pain, or longevity, of pain relief. In addition, the request does not include the frequency. In addition, there was a lack of evidence regarding the outcome measurements of conservative care such as, physical therapy or home exercise regimen outcome improvements noted for the injured worker. There was no urine drug screen submitted to indicate an opioid compliance for the injured worker. The request submitted failed to indicate frequency and duration of medication. Given the above, the request for Synapryn 10 mg/1ml oral suspension 500ml is not supported by the California Medical Treatment Utilization Schedule (MTUS) Guidelines recommendations. As such, the request is not medically necessary.

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

**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) Page(s): 41.

**Decision rationale:** The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine (Flexeril), page 41. The Expert Reviewer's decision rationale: According California (MTUS) Chronic Pain Medical Guidelines recommends, "Flexeril as an option, using a short course therapy. Tabradol (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better." Treatment should be brief. There is also a post-operative use. The addition of Tabradol to other agents is not recommended. Tabradol treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. Tabradol is closely related to the tricyclic antidepressants and amitriptyline. The documentation submitted lacked evidence of outcome measurements of conservative care such as prior physical therapy sessions and medication pain management. There was lack of documentation provided on her long term-goals of functional improvement of her home exercise regimen. In addition, the request lacked frequency, quantity and duration of the medication. As, such, the request for Tabradol 1mg/ml 250ml is not medically necessary.

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

**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 Proton pump inhibitors Page(s): 68-69.

**Decision rationale:** The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Proton pump inhibitors, pages 68-69. The Expert Reviewer's decision rationale: Prilosec is recommended for patients taking NSAIDs who are at risk of gastrointestinal events. The documentation submitted did not indicate the injured worker having gastrointestinal events. The provider failed to indicate the frequency and quantity medication on the request that was submitted. In addition, the provider failed to indicate long term functional goals or medication pain management outcome measurements for the injured worker. Given the above, the request for Deprizine 15mg/ml 250ml is not medically necessary.

**Dicopanol 5mg/ml 150 ml:** 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 ODG - Pain (Chronic) Insomnia Treatment.

**Decision rationale:** The Expert Reviewer based his/her decision on the Non-MTUS ODG - Pain (Chronic) Insomnia Treatment. The Expert Reviewer's decision rationale: According to Official Disability Guidelines (ODG), "Over-the-counter medications: such as Dicopanol are sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine)." Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. The documents submitted for review failed to indicate the long-term functional goals for the injured worker to include medication management. The request failed to indicate frequency and duration of medication. Given the above the request for Dicopanol 5mg is not medically necessary.

**Fenatrex 25mg/ml 450 ml:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Specific drug list, Gabapentin Page(s): 16.

**Decision rationale:** The Expert Reviewer based his/her decision on the MTUS Chronic Pain Medical Treatment Guidelines, Specific Drug List, Gabapentin, page 16. The Expert Reviewer's decision rationale: The California MTUS guidelines indicate that Gabapentin is 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. There is a lack of documentation of

efficacy and functional improvement with the use of this medication. In addition, it was not indicated how long the injured worker had been utilizing this medication. Moreover, the request does not indicate a frequency for this medication. Therefore, the request is not medically necessary.